£7.4 million in 2002 for the same products and at PPP prices²¹. This, expressed as a proportion of total sales for the 19 products we examined, ranged between 4.3% and 5.3%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter comes from the lowest PPP price in the EU. Gross profits from simvastatin, and citalopram, two products generating significant savings in Denmark and had large market shares in 2002, account for over three quarters of all gross profits (Table 6.1). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Denmark was 38% in 2002 for the 19 products we examined, ranging from 9% (for sertraline) to 60% (for clozapine) (Table 6.18).

6.1.6. Impact on industry

The direct impact on industry in Denmark is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Denmark for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this study, the total loss of profitability to industry ranges from €9,029.3 million to €10,373.2 million.

²¹ We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figures for Denmark are ϵ 1,071 (annual fee) and ϵ 2,033.4 (application fee) to obtain marketing authorization for 5 years.

6.1.7. Overall conclusions

Prices of PI medicines are on average 8.4% lower than those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 28.1% of the brand retail market. Few products yield significant savings to health insurance and, by implication, significant profits to parallel importers. Within the context of the Danish health care system and its cost-sharing structure, patients can benefit modestly if their condition is acute and requires extensive treatment with medications. Pharmacists have neither incentives nor disincentives to dispense PI drugs but are obliged to do so by the Danish substitution laws, if a PI drug is available. Pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by the health care system to the order of 2.2%. The majority of pecuniary benefits accrue to parallel importers, and less so to the health service by a ratio of 2.01:1 – 2.46:1. Industry incurs a loss in market share in Denmark and a significant loss in profits, which are re-distributed to health insurance and parallel importers.

6.2. Germany

6.2.1. General trends

The total sales of the 19 products selected, were €2.21 billion at PPP level, or just under 13% of the German brand prescription medicines market (see Table 6.3). Statins feature prominently, and account for 35% of total sales in the sample. Enalapril, ramipril, omeprazole, and pantoprazole also feature strongly (7%, 5%, 16% and 9% of total sample sales, respectively). With the exception of olanzapine, risperidone, lansoprazole and fluoxetine that have PI penetration (market shares) greater than 35% (62%, 62%, 39% and 37%, respectively), and citalopram and paroxetine with market shares between 28-30%, in all other products, PI market shares range from 1-11% (Table 6.3, column 4). The weighted average market share of PI for all 19 products was 13.5% of the branded retail market. For 11 out of 19 products examined in 2002, the average price spread between locally-sourced and PI product in the German market was 10% or lower. Price spreads are higher than 10% for lansoprazole (11%), pantoprazole (11%), fluoxetine (21%), paroxetine (15%), and enalapril (13%). For 3 products (atorvastatin, losartan, and clozapine), there were no PI in 2002. The weighted average price spread between locally-sourced and PI products, like for like, was 6.7% in 2002 (Table 6.3, column 5). Products with small PI market shares offer higher discounts on average compared with those with large market shares, although this principle does not always hold.

6.2.2. Benefits to health insurance

From equation (3.5) we were able to calculate the direct savings to sickness funds and from equation (3.6) we were able to denominate these as a proportion of the total sales

for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total savings to health insurance from the 19 products examined amounted to just over €17.7 million, expressed at PPP level in 2002. Two products (olanzapine and risperidone) account for over half (54%) of all reported savings to the sickness funds, whereas further 4 products (simvastatin, lansoprazole, pantoprazole, and paroxetine) yield benefits to sickness funds exceeding €1 million each (see **Table 6.3**). Six products (pravastatin, captopril, enalapril, quinapril, ramipril and omeprazole) yield savings below €100,000 each. No parallel imports were recorded for atorvastatin and clozapine in 2002. Consequently, financial benefits to sickness funds are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total product sales, direct financial benefits to sickness funds, ranged between 0.004% - 3.5%, the only outliers being risperidone (6.5%) and lansoprazole (6.2%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 0.8%.

We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentations that yield the highest (proportionately) savings to health insurance. In **Table 6.4**, and for the product with the highest market penetration in the German market (risperidone), we confirm that the majority of savings to health insurance (60%) accrue from just four (out of the 23 available) product presentations. The most popular presentation yields 26.2% of the total product savings.

6.2.3. Benefits to patients

The products we have considered in this exercise are prescription only medicines and, as such, are subject to modest co-payments by patients, which are related to the product's pack size. Any additional co-payments relate to the difference between the reference price and the drug of choice.

Within the context of the current exercise, patients cannot draw any benefit from parallel trade in Germany, since the cost-sharing structure is a fixed fee related to pack size, alongside a reference pricing system mostly in patent-expired medicines, which has practically no implications for the cost of PI medicines to patients. Furthermore, any price difference between locally-sourced and PI products accrues to sickness funds. We can therefore attribute the benefits to patients to be zero. This does not lend any support to the argument that lower prices from parallel trade also benefit patients via improved access to medicines. This argument might only have validity in the case where patients receive their medications on the basis of private prescriptions and, consequently, have to bear the entire cost out-of-pocket. In this case, any price difference between the locally-sourced and the equivalent PI product would accrue to the patient rather than the insurance company, so long as the latter did not have a prescription drug benefit in place similar to that provided by statutory health insurance.

6.2.4. Benefits to pharmacists

Pharmacists do not benefit directly from parallel trade as they had to observe their PI quota in 2002 as well as operate in a fixed margins environment. The latter, in principle, does not allow (significant) discounts from wholesalers, although, as discussed previously, in practice discounts are routinely offered; however, their extent is unknown or can be traced with difficulty and may be product specific. Consequently, direct and visible financial benefits to pharmacists are zero, whereas there may be positive but invisible financial benefits to them.

6.2.5. Benefits to parallel importers

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of sickness fund financial benefits, and ranged between €80.3 million and €98 million in 2002 for the same products and at PPP prices²². Expressed as a proportion of total sales for the 19 products we examined, these benefits ranged between 3.6% and 4.4%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the lowest PPP price in the EU. Gross profits from olanzapine and risperidone, the two most heavily PI products in the German market, account for just under two thirds of all gross profits (**Table 6.3**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Germany was 53% in 2002 for the 19 products we examined, ranging from 23% (for pravastatin) to 92% (for captopril) (Table 6.18).

²² We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for Germany is €1,380 to obtain marketing authorization for 5 years.

6.2.6. Impact on industry

The direct impact on industry in Germany is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Germany for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this study, the total loss of profitability to industry ranges from €98 million to €115.7 million.

6.2.7. Overall conclusions

The spread between prices of locally-sourced versus PI medicines is on average 6.7% and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 13.5% of the brand retail market. Few products yield significant savings to health insurance and, equally, few products yield significant profits to parallel importers. Patients cannot benefit directly in a market where the majority of products are reimbursed by health insurance; however, they could benefit financially (by the price difference between locally sourced and PI product) if they obtain a prescription for a product that is not reimbursed by health insurance. Pharmacists faced a 5.5% PI quota in 2002 (and an even higher one in 2003) and can incur penalties if they do not dispense a PI drug if the latter is available. Pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by sickness funds to the order of 0.8%. The majority of pecuniary benefits accrue to parallel importers, and less so to sickness

funds by a ratio of 4.53:1 to 5.53:1. Industry incurs a loss in market share in Germany and a significant loss in profits, which are re-distributed to health insurance and, mostly, to parallel importers.

6.3. The Netherlands

6.3.1. General trends

The total sales of the 19 products selected, were €524.9 million at PPP level, or just under 28% of the Dutch brand prescription medicines market (see Table 6.5). Statins feature prominently, and account for 42% of total sales in the sample, of which 16% is the market share for atorvastatin and 17% the market share for simvastatin. Omeprazole also features (25% of total sample sales), but all other drugs have small market shares. With the exception of simvastatin, risperidone and fluoxetine that have PI penetration (market shares) greater than 33% (51%, 33% and 34%, respectively), and citalopram, quinapril, valsartan, lansoprazole, and ramipril with market shares between 14-21%, in all other products PI market shares range from 0-11% (Table 6.5, column 4). The weighted average market share of PI for all 19 products was 19% of the branded retail market. In 2002, and for 11 out of 19 products examined, the average price spread between locally-sourced and PI in the Dutch market was 12% or lower. Price spreads were higher than 12% for pantoprazole (25%), losartan (23%), simyastatin (22%), omeprazole (18%), paroxetine (18%), olanzapine (15%), paroxetine (18%), and valsartan (13%). For 1 product (captopril), there were no PI in 2002. The weighted average price spread between locally-sourced and PI product, like for like, was 15.8% in 2002 (Table 6.5, column 5), significantly higher than those found in Denmark, Germany, Sweden, or the UK.

6.3.2. Benefits to health insurance

In the Netherlands, the direct benefits to health insurance arise from two sources: first, price differences between locally-sourced and PI product in the Dutch market and, second, the clawback. In the Netherlands, we have calculated the impact of the clawback as 6.82% off the total sales of PI medicines.

With regards to direct price effects, from equation (3.5) we were able to calculate the direct savings to the Dutch sickness funds arising from price differences between locally-sourced and PI products and from equation (3.6) we were able to denominate these as a proportion of the total sales for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total savings to health insurance from the 19 products examined amounted to just over €12.7 million, expressed at PPP level in 2002. Three products (atorvastatin, simvastatin and omeprazole) account for 82% of all reported savings to sickness funds from this source, whereas further 3 products (quinapril, risperidone, and pantoprazole) yield benefits to sickness funds between €300,000 and €600,000 each (see Table 6.5). Four products (pravastatin, ramipril, fluoxetine, and sertraline) yield savings of just over €100,000 each. Again, financial benefits to sickness funds are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total branded product sales, direct financial benefits to sickness funds, ranged between 0.03% -2.9%, the only outliers being simvastatin (5.7%), fluoxetine (5.6%) and quinapril (5.3%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 2.4%.

With regards to savings accruing to sickness funds from the clawback, we applied the fixed clawback rate of 6.82% off the prices of total PI volumes. Savings from this source amount to €6.4 million, raising the total savings to health insurance funds to €19.1 million (**Table 6.5**, column 7), or 3.6% as a proportion of total branded sales for the 19 products in our sample.

We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentations that yield the majority of savings to health insurance. In **Table 6.6**, and for the product with the highest market penetration in the Dutch market (simvastatin), we confirm that all savings to health insurance accrue from just two presentations (20mg/30 pack; and 40mg/30 pack). The most popular presentation yields 63.2% of total product savings.

In the Netherlands we were also able to determine the source of parallel imports for all products in our sample. In **Tables 6.7-1 to 6.7-6**, we present the source of parallel imports for three products with the highest PI penetration (simvastatin, fluoxetine, and risperidone), and also a breakdown of the source by product presentation. For all three products, the majority of PI into the Netherlands comes from the lowest-priced countries, although, occasionally, higher-priced countries also feature (e.g. the UK accounts for 3.7% of simvastatin parallel exports to the Netherlands in 2002). This observation further re-enforces our original hypothesis that although nowadays parallel trade is a more generalised phenomenon taking place between countries that display *some* price differences for the same product, the majority of it still comes from lower-price countries, where the price spread is stil significant.

6.3.3. Benefits to patients

The products we have considered in this exercise are prescription only medicines and, as such, are not subject to co-payments by patients. The Dutch reference pricing system clusters similar products together and patients have to pay the difference between the cost of the drug reimbursed by health insurance and the

cost of their drug of choice, should that be different from what is reimbursed. Patient liability to paying the cost in excess of the reference price is waived if there are medical reasons for the drug of choice to be prescribed.

Consequently, within the context of the current exercise, patients cannot draw any direct benefit from parallel trade in the Netherlands. As discussed previously, any price difference between locally-sourced and PI products is split between the sickness funds and pharmacists. We can therefore attribute the benefits to patients to be zero. This does not lend any support to the argument that lower prices from parallel trade also benefit patients directly and, in doing so, patient access to medicines is improved. This argument might only have validity in the case where patients receive their medications on the basis of private prescriptions and, therefore, have to bear the entire cost out-of-pocket. In this case, any price difference between the locally-sourced and the equivalent PI product would accrue to the patient rather than the insurance companies. This may be the case for life-style drugs which are typically not reimbursed by the sickness funds (see section 4 of this paper).

6.3.4. Benefits to pharmacists

In the Netherlands, pharmacists have incentives to dispense a PI drug on two counts. First, because up until recently, 33% of the price difference between locally-sourced and PI pharmaceuticals accrued to them.²³ Despite recent changes in policy, we have maintained the 67-33% split in the distribution of potential savings from parallel imports. The second source of income to Dutch pharmacies is the discounts offered to them by wholesalers and parallel importers. We are not in a position to

²³ This policy was subsequently replaced by a fixed fee of €0.14 per script, which is almost equivalent to 33% of the relevant price difference. This last shift in policy also reflects the fact that price differences should no longer be the sources of *additional* income to pharmacists, but should form part of the pharmacy's *regular* remuneration for services provided. This fee applies to all drugs.

know the actual discounts with precision, as these are product-specific, but some sources elevate these up to 20% off the list price. The Dutch government recognises that this is a significant form of additional income to pharmacies and reimburses them at the list price minus 6.82% (up to a maximum of 6.40 per script), which is the clawback in the Dutch case. The remainder of the actual discount accrues to pharmacies. On the basis of the above, the direct financial impact on pharmacies due to price differences in the 19 products of our sample is in the region of 6.4 million. As discussed above, this would be enhanced by the actual discount they receive from parallel importers minus the clawback. This 'residual' discount would, of course, reduce the gross revenues to parallel importers.

6.3.5. Benefits to parallel importers

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of sickness fund financial benefits, and ranged between €38.3 million and €49.7 million in 2002 for the same products and at PPP prices. Expressed as a proportion of total sales for the 19 products we examined, gross profits ranged between 7.3% and 9.5% and were the highest proportional rates for all countries studied. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the

²⁴ We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for the Netherlands is €1,021 per year to obtain (and retain) marketing authorization which remains valid for as long as the branded equivalent product has marketing authorisation.

lowest PPP price in the EU. Gross profits from simvastatin alone, the product with the highest PI penetration in the Dutch market, accounts for 52% of all gross profits (Table 6.5). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found the average mark up in the Netherlands to be 51% in 2002 for the 19 products we examined, ranging from 25% (for pravastatin) to 67% (for lansoprazole) (Table 6.18).

When the effect of the clawback is added, profits to parallel importers decline, and the range is €33.7 million to €43.2 million. The average mark-up in this case is 32% (with 14% for pravastatin and 49% for lansoprazole). As already mentioned above, we are not in a position to know with precision the value of the actual discounts to pharmacy from parallel traders, therefore, our profit estimates for the Netherlands are over-estimates. However, the differential discount (i.e. actual discount offered by parallel traders minus the clawback) accrues to pharmacies and not sickness funds. Consequently, it does not benefit patients directly or indirectly.

6.3.6. Impact on industry

The direct impact on industry in the Netherlands is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and the Netherlands for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this

study, the total loss of profitability to industry ranges from €57.5 million to €68.9 million.

6.3.7. Overall conclusions

Prices of PI medicines are on average 15.8% lower than those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The price spread (15.8%) between locally-sourced and PI products is highest in the Netherlands than any other study country. The extent of parallel trade has increased over time and in 2002 accounted for 19% of the brand retail market in our sample. Few products yield significant savings to health insurance and, by implication, significant profits to parallel importers. Patients cannot benefit directly in a market where the majority of products are reimbursed by health insurance, but could benefit (by the price difference between locally sourced and PI product) if they obtain a prescription for a product that is not reimbursed by health insurance, should that product be available as PI. Pharmacists do benefit in the Netherlands through price differences and the discounts they receive from parallel traders and wholesalers. Overall, pharmaceutical parallel trade does have a moderate direct financial impact on the total cost of medicines reimbursed by sickness funds to the order of 2.4% - 3.6%. The majority of pecuniary benefits accrue to parallel importers, and less so to sickness funds by a ratio of 3.00:1 to 3.9:1 (without the clawback) and 1.76:1 to 2.26:1 (with the clawback). Industry incurs a loss in market share in the Netherlands and a significant loss in profits, which are re-distributed to health insurance, pharmacists and parallel importers.

6.4. Norway

6.4.1. General trends

The total sales of the 19 products selected, were €196.4 million at PPP level, or just under 24% of the Norwegian brand prescription medicines market (see Table 6.8). Statins feature prominently, and account for 40% of total sales in the sample, of which simvastatin had a 27% overall market share. Citalopram, pravastatin, omeprazole, and olanzapine also feature strongly (11%, 8%, 8% and 7% market share of total sample sales, respectively). With the exception of simvastatin, risperidone, and clozapine that have PI penetration (market shares) greater than 35% (36%, 42%, and 58%, respectively), and pravastatin and enalapril with market shares between 14-24%, in all other products, PI market shares range from 0-11% (Table 6.8, column 4). The weighted average market share of PI for all 19 products was 18.3% of the branded retail market. In 2002, and for 11 out of 19 products examined, the average price spread between locally-sourced and PI product in the Norwegian market was 6% or lower. Price spreads are higher than 6% for enalapril (25%), and fluoxetine (39%). For 6 products (quinapril, losartan, valsartan, lansoprazole, pantoprazole, and sertraline), there were no PI in 2002. The weighted average price spread between locally-sourced and PI products, like for like, was 2.5% in 2002 (Table 6.8, column 5).

6.4.2. Benefits to health insurance

In Norway, the only source of direct financial benefits to the health care system is the price difference between locally-sourced and PI products. Of this, the health service ensures it receives 50%, whereas the remaining 50% accrues to

pharmacists. From equation (3.5) we were able to calculate the direct savings to the health care system and from equation (3.6) we were able to denominate these as a proportion of the total sales for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total savings to the Norwegian health system from the 19 products examined amounted to just over £0.56 million, expressed at PPP level in 2002. Three products (simvastatin, enalapril and risperidone) account for over three quarters (76%) of all reported savings (see **Table 6.8**). Consequently, financial benefits to the health service are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total product sales, direct financial benefits to the health care system, ranged between 0.1% - 0.3%, the only outliers being enalapril (4.2%), clozapine (1.9%) and risperidone (2.7%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 0.3%.

We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentations that yield the highest (proportionately) savings to health insurance. In **Table 6.9**, and for the product with the highest market penetration in the Norwegian market (clozapine), all savings to the health care system come from one of the two presentations available for that product.

6.4.3. Benefits to patients

As discussed in section 4, the Norwegian reimbursement system, reimburses primarily the cost of medications meant for chronic conditions (subject to moderate co-payments), whereas patients are supposed to meet most of or the entire cost of their

medicines for acute conditions. Theoretically, and for acute conditions, patients would benefit by the price difference between locally sourced and PI products. As price differences between locally-sourced and PI products are split equally between the Norwegian health service and pharmacists, patients cannot benefit directly from lower prices of PI medicines.

6.4.4. Benefits to pharmacists

In Norway, pharmacists have an incentive to dispense a PI drug, since according to government policy, they are allowed to retain 50% of the price difference between locally-sourced and PI alternatives. There are no visible discounts by wholesalers, but should there be, these would presumably apply to both locally-sourced and PI drugs and, in any case, they would accrue entirely to pharmacists in the absence of any government-supported clawback system. Consequently, we calculated the extra revenue accruing to pharmacists from parallel imports as 50% of the price difference between locally-sourced and PI drugs times the PI volume for each drug. This was €0.56 million in 2002, or 0.3% of total brand sales for the 19 sample products.

6.4.5. Benefits to parallel importers

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of sickness fund financial benefits, and ranged between €7.5 million and €12.4 million

in 2002 for the same products and at PPP level²⁵. This, expressed as a proportion of total sales for the 19 products we examined, ranged between 3.8% and 6.3%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the lowest PPP price in the EU. Gross profits from simvastatin, a product with one of the highest PI market penetration in the Norwegian market, account for just under two thirds of all gross profits (**Table 6.8**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Norway was 46% in 2002 for the 19 products we examined, ranging from 14% (for fluoxetine) to 76% (for captopril) (**Table 6.18**).

6.4.6. Impact on industry

The direct impact on industry in Norway is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Norway for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to sickness funds plus the gross profits to parallel importers. For the 19 products included in this study, the total loss of profitability to industry ranges from €8.6 million to €13.6 million.

 $^{^{25}}$ We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for Norway ranges from 68,489-69,701.8 to obtain marketing authorization for 5 years on the understanding that the product in question has been marketed in the European Economic Area (EEA) for 6 years. An additional control fee of 0.7% of the turnover of the MA holder is applied to the above figures.

6.4.7. Overall conclusions

Prices of PI medicines are on average 2.5% lower than those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 18.3% of the brand retail market. Few products yield significant savings to health insurance and, by implication, significant profits to parallel importers. Patients may in a position to benefit directly if treatment is for acute rather than chronic conditions, although these benefits are, on average, 2.5% for all products in the sample, and depend on the product in question. Pharmacists also benefit by keeping 50% of the price difference between locally sourced and parallel imported products.

Therefore, pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by sickness funds to the order of 0.3%. The majority of pecuniary benefits accrue to parallel importers, and less so to the Norwegian health service by a ratio of 13.7:1 to 22.6:1. Industry incurs a loss in market share in Norway and a significant loss in profits, which are re-distributed to health insurance, pharmacists and parallel importers.

6.5. Sweden

6.5.1. General trends

The total sales of the 19 products selected, were €353.7 million at PPP level, or just under 19% of the Swedish brand prescription medicines market (see **Table 6.10**). Statins feature prominently, and account for 34% of total sales in the sample. Simvastatin, omeprazole, lansoprazole, and atorvastatin feature strongly (21%, 16.4%, 10.6%, 9.2% and 9.6% of total sample sales, respectively). With the exception of clozapine, paroxetine, and risperidone that have PI penetration (market shares) greater than 30% (74%, 47%, 32%, respectively), and a further 8 products with market shares between 8-30%, the remaining 7 products did not register any PI (**Table 6.10**, column 4). The weighted average market share of PI for all 19 products was 31% of the branded retail market. In 2002, and for 11 out of 19 products examined, the average price spread between locally-sourced and PI product in the Swedish market was 15% or lower. Price spreads are higher than 15% for clozapine (17%), fluoxetine (18%), and omeprazole (19%). The weighted average price spread between locally-sourced and PI product, like for like, was 2.2% in 2002 (**Table 6.10**, column 5).

6.5.2. Benefits to the Swedish health care system

In Sweden, the only source of direct financial benefits to the health care system are related to the price difference between locally-sourced and PI products. From equation (3.5) we were able to calculate the direct savings to the health system and from equation (3.6) we were able to denominate these as a proportion of the total sales for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved. On the basis of IMS data, the total

savings to health insurance from the 19 products examined amounted to just over €3.7 million, expressed at PPP level in 2002. Three products (sertraline, risperidone, and omeprazole) account for over half (52%) of all reported savings to the health care system, whereas 3 more products (olanzapine, ramipril, and atorvastatin) yield benefits to the health system exceeding €0.25 million each (see **Table 6.10**). No parallel imports were recorded for six products in 2002 (simvastatin, captopril, quinapril, losatran, valsartan and pantoprazole). Consequently, financial benefits to the health service are concentrated in a handful of products, whereas for the remainder, direct financial benefits are very small. As a proportion of total product sales, direct financial benefits, ranged between 0.3% - 3.4%, the only outliers being fluoxetine (4.6%), risperidone (4.9%), and clozapine (19.5%). Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 1.3%.

We were able to calculate savings on a product-by-product and presentation-by-presentation basis. Whereas several product presentations are available for a given product, it is usually the most popular presentations that yield the highest savings to health insurance. In **Table 6.11**, and for the product with the highest market penetration in the Swedish market (clozapine), we confirm that all savings to health insurance accrue from just two presentations (100mg/100 pack; and 25mg/100 pack). The most popular of the two presentations yields 93% of the total product savings.

6.5.3. Benefits to patients

Despite the structure of cost-sharing in Sweden that would theoretically allow patients to benefit directly from parallel importation, any price difference between locally-sourced and PI products accrues to the health service; consequently, direct patient benefits are zero in the Swedish case.

6.5.4. Benefits to pharmacists

In Sweden, pharmacists do not benefit directly from parallel trade as they operate in a fixed margins environment. The latter, in principle, does not allow (significant) discounts from wholesalers, although, as discussed previously, in practice discounts are routinely offered, however, their extent is unknown or can be traced with difficulty and may be product specific. In Sweden, Apoteket is remunerated for its work on generics and parallel imports, but this is an ex-post, one-off payment annually, bundled together for generics and parallel imports (SKr 50 million or €5.5 million in 2002). Consequently, direct and visible financial benefits to pharmacists are zero, but they may receive one-off bonus payments.

6.5.5. Benefits to parallel importers

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of sickness fund financial benefits, and ranged between €16.7 million and €18.4 million in 2002 for the same products and at PPP prices²⁶. This, expressed as a proportion of total sales for the 19 products we examined, ranged between 4.7% and 5.2%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the lowest PPP price in the EU. Gross profits from three of the

 $^{^{26}}$ We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for Sweden is £1,637 to obtain marketing authorization for 5 years.

products with the highest market shares (olanzapine, risperidone and paroxetine), account for 55% of all gross profits (**Table 6.10**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in Sweden was 12% in 2002 for the 19 products we examined, ranging from 9% (for atorvastatin, pravastatin, ramipril and citalopram) to 46% (for sertraline) (**Table 6.18**).

6.5.6. Impact on industry

The direct impact on industry in Sweden is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and Sweden for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to the health care system plus the gross profits to parallel importers and direct benefits to patients. For the 19 products included in this study, the total loss of profitability to industry ranges from €20.5 million to €22.2 million.

6.5.7. Overall conclusions

Prices of PI medicines in Sweden are on average 2.2% lower than those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 31% of the brand retail market. As in all previous country case studies, few products yield significant savings to the health service and significant profits to parallel importers. Patients could benefit directly because of the structure of co-payments in Sweden, but

such benefits are marginal if pharmaceuticals are in principle reimbursed by health insurance. Pharmacists do not have financial incentives to dispense PI drugs but dispensing them is compulsory under Swedish substitution laws. In addition, pharmacies receive a lump sum for their work on generics and PI. Pharmaceutical parallel trade does have a modest direct financial impact on the total cost of medicines reimbursed by sickness funds to the order of 1.3%. The majority of pecuniary benefits accrue to parallel importers, and less so to sickness funds by a ratio of 4.44:1 to 4.89:1. Industry incurs a loss in market share in Sweden and a significant loss in profits, which are re-distributed to health insurance, parallel importers and, less so, to patients.

6.6. United Kingdom

6.6.1. General trends

The total sales of the 19 products selected, were €1.97 billion at PPP level, or just under 24% of the UK brand prescription medicines market (see Table 6.12). Statins feature prominently, and account for 47% of total sales in the sample, of which simvastatin accounted for 25% and atorvastatin for 15% of total sample sales. Lansoprazole, omeprazole, and olanzapine also feature strongly (13.1%, 8.9%, and 6.3% of total sample sales, respectively). Market penetration in the UK is quite high and exceeds 50% in 3 products (losartan, 72%; simvastatin, 65%; and atorvastatin, 54%). Five other products have market shares greater than 30% (olanzapine, 47%; risperidone, 45%; pravastatin, 38%; pantoprazole, 32%; and lansoprazole, 31%, respectively). In all other products PI market shares range between 2-25% (Table **6.12**, column 4). The weighted average market share of PI for all 19 products was 27.4% of the branded retail market, the highest in the study countries. In 2002, and for 14 out of 19 products examined, the average price spread between locally-sourced and PI product in the UK market was zero. The exception were fluoxetine (9% spread), paroxetine (34% spread) and pravastatin (0.001% spread). There were no PIs for ramipril and clozapine in 2002. The weighted average price spread between locallysourced and PI product, like for like, was 2.2% in 2002 (Table 6.12, column 5).

6.6.2. Benefits to the British NHS

In the UK, the sources of direct financial benefits to the NHS are twofold: direct effects from price differences between locally-sourced and PI products and the clawback. From equation (3.5) we were able to calculate the direct savings to the

NHS and from equation (3.6) we were able to denominate these as a proportion of the total sales for the 19 products in our sample in 2002. Savings were calculated for all product presentations for each of the products involved (see **Table 6.13**). On the basis of IMS data, the total visible savings to the NHS from the 19 products examined amounted to just over €6.8 million, expressed at PPP level in 2002. Paroxetine accounts for 97% of these savings (**Table 6.12**). No parallel imports were recorded for ramipril and clozapine in 2002. Consequently, financial benefits to the NHS are concentrated in two products, whereas for the remainder, direct financial benefits are zero. Total savings for all 19 products, as a proportion of total branded sales at PPP level stood at 0.3%.

With regards to savings accruing to the NHS from the clawback, we had no means of calculating these with precision, as this would involve knowing the level of discount offered to pharmacies by wholesalers/parallel traders on each product. This is confidential commercial information and, although, some evidence exists about average discounts for top-selling products^{cix} this might not be representative of the situation in individual products. In order to provide some measure of the likely effect of the clawback in the UK, we approached this from a macroeconomic perspective and used the estimates of the UK government, which amounted to £100 million for 2001-2002 (£144 million). Considering that our sample of products (which accounts for just under 24% of the UK brand prescription medicines market) has five of the top-15 selling products in terms of PI, and judging by other observations that the top-10 selling PI products typically yield more than 50% of benefits to health insurance, we took our entire sample of 19 products to yield more than its relative weight in

terms of clawback revenue and assumed that to be a third (33%) of the total savings from the clawback for 2002.²⁷

6.6.3. Benefits to patients

The impact on patients in the UK from parallel imports is zero.

6.6.4. Benefits to pharmacists

In the UK, pharmacies receive discounts offered to them by wholesalers and parallel importers. Confidential annual discount inquiries are conducted by the UK government to determine the clawback, but, as mentioned above, we have no access to these discounts, therefore, it is impossible to calculate with accuracy the additional revenue that accrues to pharmacies. We recognize that the average clawback taken by the UK government is in the region of 10.44% and it is highly likely that pharmacists still retain a certain margin on top of that ("differential discount").

It is, therefore, recognised that pharmacies retain a (significant) amount as income from the discounts they receive, that this income is beyond the clawback and does not accrue to the NHS, and that, accordingly, parallel importers' gross revenues should be somewhat lower if this source is also taken into account.

Pharmacists would also benefit from the private prescription market as in this particular case there is no clawback and any discounts offered to pharmacies should accrue to them entirely.²⁸

²⁷ This may not necessarily be a scientific way of arriving at a figure, and is probably an over-rather than an under-estimate, if the UK government's figures are correct. It also does not take into account the effect of the "differential discount" on pharmacies, i.e. the additional income that pharmacists receive after the clawback has been returned to the UK DoH/Treasury.

²⁸ We are grateful to a referee for pointing this out.

6.6.5. Benefits to parallel importers

Based on equation 3.7 we were able to derive parallel importers' maximum gross financial benefits. We applied the principle of the lowest priced country as the sole source of PI for a particular product formulation as well as the principle of the three lowest priced EU countries for the same purpose. We find that by applying either principle, gross financial benefits accruing to parallel importers are a multiple of financial benefits accruing to the NHS, and ranged between €518 million and €414 million in 2002 for the same products and at PPP prices²⁹. This, expressed as a proportion of total sales for the 19 products we examined, ranged between 21% and 26.3%. The former figure relates to the average of the three lowest EU PP Prices, whereas the latter from the lowest PPP price in the EU. The above figures are reduced to €469 million and €365 million respectively (or 23.8% and 18.5% of total sales respectively), if the effect of the clawback is included.

Gross profits from atorvastatin, and simvastatin, the two most heavily PI products in the UK market, account for 60% of all gross profits (**Table 6.12**). Based on equation 3.8, which indicates the PI mark-up defined as gross profit from parallel import activities over total revenue from the same activities, we found that the average mark up in the UK was 54% in 2002 for the 19 products we examined, ranging from 21% (for lansoprazole) to 72% (for omeprazole) (**Table 6.18**).

6.6.6. Impact on industry

The direct impact on industry in the UK is a net loss of both market share and profits. Local industry affiliates lose market share to parallel imports, which would

²⁹ We are not in a position to calculate net financial benefits due to the lack of information on parallel importers' costs, which include transportation, storage, distribution and regulatory. Of these, we have already provided benchmark figures from regulatory authorities throughout the EU on obtaining marketing authorization for a PI pharmaceutical (**Table 3.3**). The figure for the UK is ϵ 2,125 to obtain marketing authorization for 5 years.

register as an increase in turnover in the source countries. More importantly, however, industry registers a loss in profitability, equivalent to the price difference between the source country and the UK for the total volume of parallel trade. In other words, industry's total profit loss amounts to the savings accruing to the NHS through price differences and the clawback plus the gross profits to parallel importers plus pharmacy revenues from discounts. For the 19 products included in this study, the total loss of profitability to industry ranges from €421,250 million to €524,900 million. This includes the unknown effect of "differential discounts" to pharmacies from parallel traders, which would register as a re-allocation from gross profits to parallel traders to income for pharmacists.

6.6.7. Overall conclusions

In the UK, prices of PI medicines are on average the same compared with those of locally sourced equivalents and penetration rates of PI medicines vary significantly. The extent of parallel trade has increased over time and in 2002 accounted for 27.4% of the brand retail market. However, the apportionment of financial benefits to the various stakeholders in the UK is difficult and can only be made with approximation due to the discount system and the clawback. There are very modest direct savings accruing to the NHS due to price differences, but it is understood that the clawback (of which only estimates exist) makes up for this shortfall. Pharmacists have an incentive to dispense a PI medicine as they receive discounts from wholesalers, which the government subsequently attempts to claw back. There are clear financial benefits to pharmacies from this process, nevertheless, these are very difficult to quantify. Patients cannot benefit directly from parallel trade in the UK. Overall, pharmaceutical parallel trade does have a modest direct financial

impact on the total cost of branded medicines reimbursed by the NHS to the order of 0.3% (without the clawback) and 2.8% (with the clawback). Whether with or without the clawback, the majority of pecuniary benefits accrue to parallel importers compared with the NHS, by a ratio of 60.2:1 to 75.2:1 (without the clawback) and 8.37:1 to 6.52:1 (with the clawback). Industry incurs a loss in market share in the UK and a significant loss in profits, which are re-distributed to the NHS, pharmacists and parallel importers.

6.7. Overall direct effects

Tables 6.15 - 6.21 present some aggregate figures on the impact of pharmaceutical parallel trade on all stakeholders. The total market penetration from parallel trade across 6 product categories and all 6 study countries was 25% of total retail brand sales in 2002 (see Table 6.20). The overall savings to health insurance organisations are modest both in absolute and relative terms and amount to €44.7 million (or €100 million with the clawback), or 0.8% as a proportion of total retail brand sales (1.8% if the clawback is included). Patients do not benefit directly, but may benefit indirectly, through savings made by health insurance, provided such savings are used to purchase care more cost-effectively. Pharmacists have modest financial benefits where incentives exist to dispense PI medicines and where the wholesale/retail market does not operate on the basis of fixed margins.³⁰ Pharmacy income in these cases can be significant, but nearly impossible to measure with accuracy, unless details on discounts become available. According to our methodology and calculations, the majority of financial benefits accrue to parallel importers (€704 million or €648.4 million if the clawback is included). The total loss of producer surplus has been calculated at €755 million for just under 22% of the retail brand market in the 6 countries and in pharmacy purchase prices. Of this between 85% and 93% accrues to parallel importers, between 5.9% and 13.2% accrues to health insurance organisations, and the remainder (approximately 1%) to

³⁰ It should be recognized, however, that even when fixed margins are in operation, there is still an opportunity for informal discounts to take place between wholesalers/parallel traders and pharmacies; these may be quantitative in nature (buy one-get one free), which would make the quantification of their impact even more difficult.

pharmacists.³¹ The ratio of gross profits to parallel traders over savings to health insurance is 16.01 (or 6.48 if the effect of the clawback is included).

Having combined data for 11 6 study countries into a panel, we conducted regression analysis on the predictors of parallel trade; we found that price differences between exporting and importing countries and parallel imports are simultaneously determined, which is consistent with the hypothesis that parallel trade is a form of arbitrage (**Table 6.21**). We find that the higher the price gap between importing and exporting countries the higher the potential for parallel trade. This result holds regardless of price gaps being estimated as endogenous. We also find that market size of the destination (importing) country, increases the flows of parallel imports. This is also confirmed by observing tables 6.1-6.12, on a country-by-country basis. Finally, parallel sales increase with a reduction of the exchange rate variability, between importing and exporting countries.

³¹ Excluding, as discussed earlier, the effect of "differential discounts" in the UK, which form part of pharmacies' income after the clawback has been deducted.

7. Competition effects within importing countries

Having assumed homogeneous products, standard economic theory postulates that (pharmaceutical) parallel trade results in (strong) price competition in destination countries, which may lead to an overall price reduction in (pharmaceutical) prices, and which, in turn, has measurable and positive impact on payers and consumers. A close look at **Table 7.1** yields a number of interesting observations about the average price spread between locally-sourced and PI products in 2002:

- First, the average price spread within each destination country between locally sourced and PI products as a share of original prices (measured as the difference between locally sourced and CBT prices over the price of locally sourced product [(P_{orig} P_{PI})/P_{orig}]) is very small. For the majority of products, the price spread is no more than 10%.
- Second, the price spread varies both by country and by product. Price spreads are
 zero for the vast majority of our sample products in the UK, but are on average
 significant in smaller counties, such as Denmark and Sweden.
- Third, for the same product, price spreads vary significantly among countries; for
 instance, the price spread between locally sourced and PI simvastatin is 1% in
 Norway, 0% (no PT) in Sweden, 5% in Germany, 6% in Denmark and 22% in the
 Netherlands.
- Fourth, for the majority of products and across countries price spreads are lower than 10%, with the exception of the Netherlands, where price spreads seem to be on average higher than 10%.

We put the above hypothesis of price convergence from the conduct of parallel trade to the test in each of the study countries, by examining price trends over the 1997-2002 period. For each product, these comparisons were based on the most popular product presentation, matched precisely between PI and locally-sourced product, over the 1997-2002 period. The expectation would be that the intensity of parallel trade, particularly in products that had very high market penetration from parallel imports, would lead to price competition and, therefore, a downward price convergence and lower prices in the medium-term. Graphs were produced of locally-sourced and PI price trends for the most highly traded products in each study country (Figures 7.1-7.6):

- Denmark: clozapine, risperidone, simvastatin, and ramipril;
- Germany: olanzapine, risperidone, simvastatin, fluoxetine, paroxetine and lansoprazole;
- The Netherlands: paroxetine, fluoxetine, clozapine, risperidone, simvastatin, and lansoprazole;
- Norway: captopril, enalapril, omeprazole, and clozapine
- Sweden: risperidone and pravastatin
- UK: simvastatin, omeprazole, pantoprazole, pravastatin, atorvastatin, and enalapril
 The evidence presented in figures 7.1-7.6 does not suggest downward price
 convergence. Downward price trends after 2001 in fluoxetine and paroxetine are
 associated with patent expiry in these products, making them less attractive targets for
 parallel imports.

To examine statistically whether prices for locally-sourced and PI products showed any signs of convergence over the 1997-2002 period, we tested the null hypothesis (H₀) of price co-movements (i.e. whether price changes over time were equal among locally sourced and PI products) versus the alternative hypothesis (H₁) of no co-movement. A *t*-test was performed, assuming unequal variances, of the

hypothesis that the mean change is the same. The t-ratios found, are not statistically significant at 5% level for any of the products outlined above and, indeed for any product in the study countries and for study period. Therefore, our results do not reject the H₀ for each of the products shown in **Figures 7.1-7.6**, suggesting that there is price co-movement between each locally sourced and PI product. This is consistent with other similar findings across a wide range of products, suggesting that the average price change of parallel-imported goods and the original manufacturer's price is the same, both from Sweden^{cx} and from Finland.^{cxi}

Consequently, there is little evidence suggesting that prices in destination countries have been affected downwards on a sustainable basis over the 1997-2002 period as a result of parallel trade. As a result, there is little support for the argument that there are dynamic effects from the conduct of parallel trade, which arise from price competition and (downward) price convergence. The situation resembles a duopoly, whereby there is one leader (patent holder or licensee) and several followers (parallel importers). Neither has an incentive to undercut the other. Although no information can be available about how prices of locally-sourced products would have performed in the absence of parallel trade, under the circumstances, it appears that health systems do not realize any financial benefits from this source.

8. Competition effects across countries

Economic theory suggests that parallel trade results in significant redistribution from low- to high-price countries in terms of lower prices in the latter. This is the standard "arbitrage" hypothesis suggesting that "price equalisation" across countries (subject to taking into account the transaction and other costs of arbitrage) is the result of conducting parallel trade, leading to improved (allocative) efficiency in the market place. In this section we examine whether this hypothesis holds for our six study countries, by comparing pricing trends in each one of them and the remaining 12 countries in our sample.

In order to test the above hypothesis, we examined the product relative price ratios (DDD- and pack-size adjusted) of importing over exporting country (RPR = $\frac{P^{orig}}{P^{orig^*}}$). In **Table 8.1** and **Figure 8.1** we present price information development for the 1998-2002 period and for all study (destination) countries by benchmarking the (DDD- and pack-adjusted) prices in each of our study countries (P^{orig}) with the prices of the lowest (potentially exporting) country (P^{orig^*})³². The resulting relative price ratio (RPR = $\frac{P^{orig}}{P^{orig^*}}$) should exceed unity. If, over time, the ratio declines or, drops below unity, then one can argue that there is price convergence between destination and source (exporting) countries, although other confounding factors may be at play.

The RPR shown in **table 8.1** and **figure 8.1**, suggests that there is very little evidence that prices across countries and across individual products converge on a sustainable basis over time (1998 - 2002), with the exception of products for which patents have expired in some markets, where the RPR ratio drops, but not

³² Similar tests have been run for the second- and third-lowest priced country.

significantly. As **tables 8.3-8.8** also indicate, price differentials between importing countries and potentially exporting countries, remain very significant for all products in our sample.

For instance, in the case of Germany, by analyzing price trends (1997-2002) of the six most widely imported products in the German market with prices of the same substance in the lowest priced EU country, and taking their ratio, we could determine the extent to which there is price convergence for that product over time. The price ratio in all cases is clearly over unity for the entire period, indicating that German prices are always higher than those in low-price countries. What is also interesting is that for the cases of simvastatin, risperidone, olanzapine and lansoprazole, there seems to be price divergence rather than price convergence over time. The same effect holds for fluoxetine and paroxetine until 2001, whereas a downward trend appears in 2002, which may be due to these molecules' patent expiry. Similar comments can be made for the other study countries.

However, it would be methodologically incorrect to attribute any upward or downward movements of the RPR exclusively to parallel trade, as the RPR contains price movements in both the importing and the exporting country. Price movements may be due to regulatory changes (such as price freezes, price cuts, etc), currency depreciation/appreciation, patent expiry, and other exogenous factors influencing specific product markets. Similarly, it would also be perilous to compare drops or rises in the RPR at specific points in time, since, some of the confounding factors raised above, may apply to individual years and not others. Consequently, the results appearing in **Table 8.1**. and **Figure 8.1** suggest that during a period when parallel trade is on the rise, there doesn't seem to be any solid evidence of price convergence between countries that parallel-import and countries that parallel-export. Instead, price

gaps between locally sourced and parallel imported products remains over time, indicating that the rationale and potential for parallel trade continues to exist. Relative prices (RPR = $\frac{P^{orig}}{P^{orig^*}}$) indicate how high prices are in destination countries relative to source countries and have exhibited historically similar trends and co-movement in all study countries.

In addition, the coefficient of variation of locally-sourced and PI prices for each product and among destination countries was calculated. This was found to be significantly different from zero, suggesting that there is important variability in prices rather than a trend towards price convergence and a uniform price in these countries. Indeed, the coefficient of variation across destination countries is significantly different from 0, but ranges from 2.4 (Valsartan in 1997) to 0.04 (Atorvastatin in 2002). The differences suggest that there could be parallel importation even between countries which are in principle considered as parallel importers of a particular product.

It would therefore be fair to suggest that there is very limited evidence of price convergence between importing and exporting countries over time, which is not necessarily attributable to the effects of parallel trade. On the basis of the above it is not possible to accept the arbitrage hypothesis that parallel trade eventually leads to price equalisation and, as a result, to welfare benefits for consumers and/or purchasers of medicines. Different systems of drug pricing and reimbursement may well contribute to this effect and this has been shown statistically at aggregate (macroeconomic) level.

9. Overall conclusions

Drawing upon the evidence from 6 product categories (and 19 products within these), the research exercise has shown that:

- Parallel trade in pharmaceuticals has intensified since the late 1990s.
- Parallel trade in pharmaceuticals is concentrated in a small number of products.
- The price spread between exporting and importing country is a key factor (partly)
 determining the potential for parallel trade, whereas market size of the importing
 country (partly) determines its extent
- The benefits accruing to health insurance organizations are, at best, modest, either
 in absolute value terms or as a proportion of total national expenditure on branded
 medicines.
- Patients do not benefit directly from parallel trade.
- Pharmacists realize modest financial benefits in countries where there are financial incentives for them to dispense PI medicines, or where the wholesale/retail market does not operate under fixed margins. In all other countries their (measurable) benefits from parallel trade are practically zero.
- Parallel importers realize significant benefits in comparison with health insurance organizations and all other stakeholders.
- Manufacturers incur a significant loss of business in destination countries from the
 conduct of parallel trade. The loss of market share to parallel trade has become
 significant since 2000 for a number of products, particularly those under patent.
 This reduces manufacturers' overall profitability, without necessarily increasing
 societal welfare.

- The paper rejects the hypotheses of price convergence across (importing and exporting) countries, predicted by advocates of parallel trade.
- The paper also rejects the hypothesis of price competition and a downward price spiral within importing countries as a result of intensifying parallel imports from EU Member States where price levels are lower.
- As a result of the above, and taking into account that some exporting countries
 may face product shortages leads to the conclusion that the static welfare effect is
 at best neutral.

Economic theory predicts that by exercising arbitrage, price equalisation (or price approximation in the case of imperfect arbitrage) between exporting and importing countries is the result, whereby prices in parallel exporting countries rise and prices in parallel importing countries decline. Economic theory also predicts that in unregulated markets and in the absence of product differentiation, the consequence of arbitrage would be a Bertrand-type price competition game between incumbent and importer leading to a "race towards the bottom" in the importing country, where price equals marginal cost, "xiii or a Stackelberg-type situation with the originator company being the leader and the parallel traders being the follower." To that end, the welfare implications are such that consumers or their agents in high price countries may benefit from lower prices, whereas consumers in low-price countries may lose out because of price rises.

In pharmaceuticals, parallel trade comprises movements of identical products and arises from price differences across markets. Unlike pure arbitrage, pharmaceutical parallel trade is a consequence of price differences arising from heterogeneous regulation across countries. From a theoretical standpoint

pharmaceutical parallel trade would not lead to price equalization across countries so long as heterogeneous regulatory regimes continue to operate over time, but might lead to lower prices in the importing country.

By using IMS data, our analysis contradicts the standard arbitrage hypothesis of price competition and race towards the bottom in the importing countries, and rejects the hypothesis of price convergence among exporting and importing countries; it also shows that there is a welfare re-allocation from industry revenue and profits to a variety of agents, most notably parallel traders and, less so, health insurance organisations. We do not find any direct pecuniary benefits to patients due to the structure of cost-sharing and the way health care goods are reimbursed by health insurance in the study countries. The question remains, whether this welfare redistribution leads to more efficient resource allocation and utilization of resources. Our analysis demonstrates that prices in exporting countries remain unchanged over time and parallel importers set prices in the importing country just under those of the originator company.

Current European law and the entire European jurisprudence on the subject, embrace the free movement of goods and the competition argument. While this is a very valid approach and in accordance with the principles of establishing an efficient internal market, due consideration ought also to be given to two further arguments: first, the public health argument and, second, the industrial policy argument.

The former argument suggests that patient access to pharmaceutical care should not be compromised; rather it should be enhanced. Within the context of parallel trade, in order to consider whether this is the case, one would need to examine what happens in both the exporting and the importing countries. In the importing country, and assuming that locally-sourced and PI products are perfect substitutes,

patient care is neither compromised, nor enhanced through the conduct of parallel trade, as patients are not benefiting directly from the effect of lower prices. In the exporting countries, however, there may be an element of compromised access. This may imply that product shortages may be observed by the pursuit of parallel trade across borders. Recent action by regulatory authorities in some member states that are predominantly parallel exporters alludes that this may be the case, and it remains to be seen how supranational authorities will react to national regulatory interventions.

The industrial policy argument highlights the importance of fostering a strong industry capable of investing all or part of its surplus on innovative R&D activities. Under systems where patents protect innovation, the legitimacy for drug manufacturers to retain a comprehensive producer surplus results from the positive impact that this might have on innovation over the long-term. The industrial policy consideration reveals an important tradeoff, namely the choice between static (allocative) and dynamic efficiency. Static efficiency refers to the short-term benefits from parallel trade, including health insurance organizations, whereas dynamic efficiency relates to the potential ability of industry to innovate over the long-term by retaining current surpluses and re-directing them to socially desirable innovation.

List of Tables and Figures

Table 3.1
Retail market shares of each of the 6 product categories as a proportion of total retail sales in each of the 6 study countries (%), 2002

	Norway	Germany	Sweden ¹	Denmark ¹	UK	Netherlands
Statins	9.9	4.6	5.5	3.6	8.0	9.1
PPI	4.1	3.4	5.1	4.0	6.3	9.4
ACE I inhibitors	1.8	2.3	1.5	1.6	4.0	3.1
ACE II inhibitors	2.2	1.4	1.4	1.5	1.8	2.0
Atypical antipsychotics	2.2	1.4	1.5	3.0	2.1	1.4
SSRI	4.3	0.9	4.4	3.6	3.8	3.4
Total	24.5%	14.0%	19.4%	17.3%	26.0%	28.4%

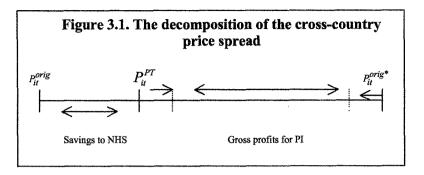
Notes: 1

Figures from Denmark and Sweden refer to the entire pharmaceutical

market (retail and hospital).

Sources:

Authors' compilations from IMS, 2002.



The Economic Impact of Pharmaceutical Parallel Trade

Special Research Paper

Table 3.2
PPP prices for 19 products adjusted by DDD and pack size

Original	Norway	Belgium	Germany	Sweden	Denmark	UK	Nether Lands	Spain	Portugal	Italy	Greece	France	Ireland	Austria
Atorvastatin	0.78	0.86	1.37	1.04	0.72	1.01	0.95	0.96	0.91	0.63	0.55	0.91	0.89	0.97
Pravastatin	1.25	1.08	1.63	1.00	0.98	1.67	1.04	1.58	1.11	0.91	0.66	1.07	1.55	0.92
Simvastatin	1.43	1.28	1.06	N/a	0.81	1.25	1.12	1.19	0.82	0.74	0.62	0.80	1.13	0.96
Captopril	0.48	0.62	0.28	0.21	0.46	0.58	0.54	0.26	0.56	0.30	0.38	0.61	0.50	0.77
Enalapril	0.25	0.29	0.20	N/a	0.22	0.59	0.30	0.19	0.28	0.28	0.19	0.46	0.41	0.24
Quinapril	N/a	0.76	0.45	0.49	0.37	0.38	0.88	0.19	0.36	0.37	0.27	0.53	0.75	0.43
Ramipril	0.32	0.51	0.48	0.31	0.17	0.60	0.69	0.21	0.28	0.24	0.18	0.40	0.35	0.36
Losartan	0.83	0.93	0.80	0.85	0.63	0.97	0.87	0.63	0.77	0.69	0.58	0.92	0.77	0.47
Valsartan	0.82	0.59	0.80	0.82	0.60	0.88	0.86	0.45	0.72	0.62	0.39	0.87	0.75	0.77
Clozapine	0.20	0.27	0.25	0.18	0.19	0.92	0.28	0.13	0.28	0.29	0.11	0.30	N/a	0.10
Olanzapine	4.80	5.60	5.78	5.37	3.81	5.48	5.19	3.57	3.90	3.60	3.30	4.83	6.07	5.28
Risperidone	3.98	4.23	5.54	4.08	2.68	5,21	5.47	2.87	3.22	2.93	2.25	3,65	5.03	5.23
Lansoprazole	1.37	2.01	1.84	1.15	0.85	1.33	1.93	1.07	0.90	1.53	1.05	1.68	1.66	1.57
Omeprazole	1.89	2.24	1.77	1.83	N/a	1.60	2.09	0.43	1.66	1.50	0.84	1.86	1.77	1.57
Pantoprazole	1.33	2.01	2.32	1.16	0.83	1.33	1.88	1.27	1.34	1.28	1.10	1.65	1.40	1.57
Citalopram	1.02	1.08	1.12	0.66	0.75	0.90	1.18	0.73	N/a	0.75	0.68	0.90	0.97	0.97
Fluoxetine	0.97	1.04	1.16	0.85	0.78	1.51	1.38	0.53	0.69	0.56	0.65	0.93	0.90	0.61
Paroxetine	N/a	1.31	1.16	0.90	0.91	0.93	1.11	0.80	0.86	0.77	0.69	0.90	0.90	0.56
Sertraline	1.08	1.22	1.11	1.12	0.82	0.85	1.31	0.72	0.76	0.87	0.55	0.84	1.36	0.88

Source: Authors' calculations from IMS.

Table 3.3

Duration of marketing authorisation and direct costs of regulatory approval for parallel imported medicines in selected European countries, 2003

2003							
Country	Duration of	Cost of obtaining marketing					
	marketing	authorisation					
	authorisation						
	5 years	Annual fee of DKK7,950 (€1,071) plus					
Denmark		application fee of DKK15,095 (€2,033.4) or					
		renewal fee of DKK13,975 (€1,882.5)					
France	No legal f	ramework on parallel imports yet					
Germany	5 years	€1,380					
Greece	5 years	€180					
Italy	5 years	€524.20 per product					
	Valid as long as						
The Netherlands	branded equivalent	€1,021 per year					
i ne Netherlands	has marketing	c1,021 por your					
	authorisation						
Portugal	N/A	N/A					
Spain	5 years	N/A					
Sweden	5 years	SEK15,000 (€1,637)					
	5 years (but normally						
	continues in force						
	only so long as both						
UK	UK licence and EEA	£1,465 (€2,125)					
	marketing						
	authorisation remain						
	in force)						
	5 years given that	NOK 70,000 – 80,000 (€8,489 - €9,701.8)					
Norway	original has been	plus control fee of 0.7% of the turnover of					
1101 WAY	marketed in EEA for	the MA holder					
	6 years						

Source:

P. Kanavos, 2003.

Table 4.1

Pricing and reimbursement methodologies in selected EU countries and
Norway, 2002-2003

	Norway, 2002-2003
Country	Main pricing/reimbursement rules relating to price setting
	a) Pricing agreement establishing pharmacy buy-in prices until June 2002
Denmark	b) Reimbursement according to Average European Price (AEP) rule
Denmark	comprising 11 EU countries plus Norway, Liechtenstein and Iceland
	c) Cost efficacy studies a requirement for price premium
	a) Free pricing for products that do not seek reimbursement
	b) 2003-2006: price notification for highly innovative products (ASMR =
	1 or 2)
	c) For other products: price fixing through negotiation with CEPS on the
France	basis of various criteria (including the product's medical value, prices
	of comparable medicines, volume sales, conditions used, industrial
	presence in the country, cost-effectiveness criteria (implicit)). If the
	reimbursement status is granted, the product will be sold on the market
·	only at the reimbursed price.
	a) Price freedom for new products
Germany	b) Reference price for off-patent sector (products subjected to generic
	competition; reference price for identical molecule only)
!	a) Price fixing for imported medicines (lowest EU price for the same
	molecule)
	b) Cannot grant a price unless product is marketed in one European
	country Providence of the control o
Cwasas	a) Requirement to be included in reimbursement lists of three of the following countries: France, Germany, Switzerland, UK, US, Sweden
Greece	b) Clustering (reference price) for calculating the average daily treatment
	cost
	c) Cost-effectiveness may be requested
	d) Lowest European price rule declared unlawful by the country's
	constitutional court in December 2001
	a) AEP (all EU countries) for 'old' products and products registered with
	the national procedure; AEP is calculated on ex-manufacturer's price
	(excluding VAT), of top five selling equivalents, including generics
	b) Price negotiation (contractual model) for new and innovative products
	for drugs registered with the EU procedures (EMEA and mutual) or for
	those for which AEP cannot be calculated
Italy	c) Price freedom for non-reimbursable drugs
·	d) New negotiation guidelines issued in February 2001 require:
	submission of cost effectiveness study, pricing and reimbursement
1	status in other countries, commitments on volume sales and discounts to
	hospitals, payback clauses or price reductions or delisting if sales rise
	above agreed levels, data on R&D and manufacturing investment in
	Italy
	a) Maximum price fixing [AEP] (twice per year) through European price
The	comparisons (reference countries are Germany, France, Belgium, UK)
Netherlands	b) AEP system giving equal weight to all alternative products (since 2000)
_ (c) Use of pharmacoeconomic studies for reimbursement of products
	requesting price premium
	a) Two-step process with MoFinance agreeing to the maximum price for
Portugal	every new product and, subsequently INFARMED processes
J	reimbursement applications h) Price Control (Average pricing of Spain France and Italy); some room
	b) Price Control (Average pricing of Spain, France and Italy); some room

	for miss magatistics
	for price negotiation
	c) Submission of 'cost-benefit' data to support reimbursement status
	d) Payback system is currently in operation until the end of 2003, whereby
	industry pays back 64.5% of any excess on agreed upon target growth
***************************************	rates
	a) Price control through negotiation on a cost-plus basis, taking into
	account expected sales and allowing specific margins for profits (12-
	18% of allowable cost), advertising (12-16% of allowable costs), and
C	R&D conducted in Spain
Spain	b) International price comparisons for active ingredient when difficulties
	arise in assessing the transfer price of a molecule
	c) Price-volume agreement for expensive products
	d) Pact stability agreement with government also promoting R&D
	e) Payback clause intensified
	a) Price control if reimbursement is sought; otherwise free pricing
	b) Reimbursement price takes into account price in 10 European
	countries; exchange rates used for conversion
	c) Price should be lower than Denmark, the Netherlands, Germany,
	Switzerland and similar to those in Norway and Finland
	d) Annual negotiations between the industry and the National Social
Sweden	Insurance Board for price revisions
	e) Price-volume agreements for innovative products
	f) No price increases are allowed for two years after launch of products
	reimbursed by RFV
	g) Products seeking price increases more than 10% after their first two
	years need to obtain RFV approval
	h) Health economic evaluation if price premium is requested
	i) Price volume agreement for innovative products
	a) PPRS: agreement with industry on profit control, renewed on 13 July
	1999, for a 5-year period
UK	b) Price cut, as part of PPRS, of 4.5%
Oik	c) Free price modulation from 1 January 2001 but keeping the 4.5% price
	cut range overall
	d) Guidance on cost-effectiveness by NICE becomes binding
	a) Free pricing unless requesting reimbursement
	b) European (EU and EEA) price comparisons, with R&D costs and
	prices of competitor products being taken into account
Norway	c) New product price setting by means of taking the average of the 2
	lowest prices of Sweden, Denmark, Finland, UK, Ireland, France,
	Germany, the Netherlands, Belgium, and Austria
	d) Prices of new and expensive products need to be ratified by Parliament
Source:	P. Kanavos (2003).
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Table 4.2

Market value of pharmaceutical parallel imports (exports) and their share

(%) of the total pharmaceutical market in selected EU countries¹

(70) OI CHE LOLA			LILUU XXX DUXU		WILLY IN	
	1997	1998	1999	2000	2001	2002
Sweden (SEK m)	270	1,012	1,402	1,732	2,011	2,309
(% of total)	1.9%	6.2%	7.7%	8.6%	9.3%	10.1%
Denmark (DKK m)	554.6	656.2	700.3	781.4	835.5	917.2
(% of total)	9.1%	10%	10%	10.2%	9.9%	9.7%
Germany (€ m)	216.7	256.6	331.1	504	800.3	1,296.3
(% of total)	1.7%	1.9%	2.3%	3.2%	4.7%	7.01%
Greece² (€ m)	14.0	107.0	173.7	308.1	514.3	556.7^3
(% of total)	0.9%	7.7%	10.7%	16.5%	24.4%	$21.6\%^{4}$
Netherlands (€ m)	357	363	374	365	424	456
(% of total)	14%	14%	14.5%	13.5%	14.3%	14%
UK (£ m) ⁵	na	462	633	749	1,076	1,346
(% of total)	na	9.5%	11.9%	13.6%	17.1%	19.8%

Data and information are not available for a number of countries as follows: (a) in France, there are currently no parallel imports and the regulatory framework is currently being set up; data for parallel exports were not available either; (b) in Italy, there is no data available because regulation for parallel imports is very general and loose. As of June 2003, there were 4 registrations for parallel imports; data on parallel exports were not available either; (c) in Portugal, there are no official data for parallel imports or parallel exports; (d) in Spain, there are no official data for parallel imports or exports; currently, there are 2 parallel imported pharmaceuticals, one from France and one from Greece.

- Data for Greece are pharmaceutical parallel *exports*.
- 3 Estimates.
- Expressed as a share of the retail market in each year.
- Official UK data (from the Prescription Pricing Authority) does not identify parallel imported products.

Source:

P. Kanavos (2003).

Table 4.3

National	policies (towards PI	pharmaceuticals	in	Europe, 2003
~ 100 02 0 22 00 0	~~~~~	· · · · · · · · · · · · · · · · · · ·	~ ~~~ ~~~ ~~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		make open and on

National policies towards PI pharmaceuticals in Europe, 2003								
Country	Policies directly en- couraging PI dispensing	Financial benefits to institutional players	Other policies benefiting PI					
(1)	(2)	(3)	(4)					
Denmark	Information Substitution No incentives to pharmacists	No financial benefits to pharmacists Health system gains through the price difference between locally sourced and PI product	Gradual movements towards the average European price – may have negative impact on PI					
France	No	No	Price notification for innovative products (those with ASMR I-II)					
Germany	 PI quota (5.5% in 2002, 7% in 2003) on pharmacy revenue Pharmacies incur penalties if quota is not met and noncash credits if they exceed it 	 Legal and contractual obligation to dispense PI drug, but no financial benefit to pharmacists; rather they may incur penalties Sickness funds benefit from the import quota set at 7% in January 2003 	No					
Greece	No	No	No					
Italy	No	No	Use of AEP to reduce potential of parallel exports					
The Netherlands	Profit share: Pharmacies retain 1/3 of price difference between locally sourced and PI drugs (or € 0.14 per script from January 1 st , 2002); the remainder accrues to sickness funds Clawback in place encouraging more costeffective purchasing by pharmacists	 Sickfunds retain 2/3 of price differential between locally sourced and PI drugs pharmacies retain 1/3 of price difference and obtain significant discounts from parallel importers 6.82% clawback in place to account for discounts offered to pharmacists or pharmacy reimbursement is X-8% or max 69 per script 	No					
Portugal	No	No	Pricing system often involves negotiations resulting in achieving AEP					
Spain	No	No	Wholesalers to register and report the destination of their products					
Sweden	 Substitution with cheaper product One-off payments to Apoteket at year-end for work on generics and PI 	 Savings in the form of price difference between locally sourced and PI accrue to LFN No direct benefits to Apoteket 	 Reduction of regulatory application fees for PI drugs Free pricing for PI drugs 					
UK	Discounts from wholesalers to pharmacists	Clawback system in operation, with average clawback being 10.4% in 2002	Free price modulation as part of the current PPRS agreement					
Norway	Equal profit sharing between pharmacies & the health service	Equal profit sharing between pharmacies & the health service	AEP may discourage overall extent of PI					

Source:

P. Kanavos, 2003.

Table 4.4
Pharmaceutical product shortages in the Greek market, 2001-2002

Pharmaceutical product shortages in the Greek market, 2001-2002								
Product	Condition for which	Product	Condition for which it					
brandname	it is used	brandname	is used					
1. Stilnox©	Tranquilliser,	19. Celestone -	Cortizone injections					
	anxiolytic, hypnotic	Chronodose©	_					
2. Mestinon©	Musculoskeletal	20. Lamictal©	Epilepsy					
3. Loramet©	Tranquilliser,	21. Imigran©	Migraine					
	anxiolytic, hypnotic	,						
4. Normison©	Tranquilliser,	22. Serevent©	Bronchodilator					
	anxiolytic, hypnotic							
5. Androcur©	Anti-androgen therapy	23. Centrac©	Tranquilliser,					
			anxiolytic, hypnotic					
6. Cyclacur©	Menstrual cycle	24. Frisium©	Tranquilliser,					
	irregularities		anxiolytic, hypnotic					
7. Colchicine©	Gouty arthritis; Acute	25. Thyrohormone;	Thyroid hormone					
	gout	Thyroxine©						
8. Plaquenil©	Anti-rheumatic; Lupus	26. Ciproxin©	Antibiotic mainly for					
			urinary tract infections					
9. Depo – Medrol©	Corticosteroid	27. Salbunova©	Bronchodilator					
10. Oruvail©	Anti-inflammatory	28. Tranxene©	Tranquilliser,					
			anxiolytic, hypnotic					
11. Romidon©	Narcotic analgesic	29. Triatec©	Hypertension					
12. Primolut©	Primary & secondary	30. Gynofen©	Oral contraceptive					
	amenhorrhea							
13. Sparine©	Tranquiliser;	31. Bezalip©	Hypercholesterolemia					
	Antipsychotic							
14. Efexor©	Tranquiliser;	32. Depakine©	Epilepsy					
	Antipsychotic							
15. Netromycin©	Antibiotic	33. Aprovel©	Hypertension					
16. Quinine©	Antifungal	34. Referan©	Dementia/Alzheimer's					
17. Sabin©	Polio vaccine	35. Xatral©	Treatment of urinary					
			symptoms of benign					
			prostatic hypertrophy					
18. Madopar©	Parkinson's disease	36. Sandostatin©	Acromegaly; GEP					
			tumours					

Source: "To Vima", 10 April 2002, based on a communication with the National Pharmacists' Association.

Table 4.5

Patient co-payments in selected EU countries and Norway, 2003 Country Type of co-payment

Adults: mix of flat fee and tiered percentages. Basic co-payment: DKr 510; Reimbursement is available at a rate of 50% for that part of the reimbursement price above DKr 510 but under DKr 1,230, at 75% for that part of the price over DKr 1,230 but under DKr 2,875, and at 85% for any amount exceeding DKr 2,875. For chronic illnesses, there is an additional threshold of DKr 3,600 beyond which all drugs are 100% reimbursed.

• Children: A similar scale as the above, but excluding the initial co-payment 0%, 35%, 65% set by the body that decides on reimbursement; co-payment levels are set on the basis of medical necessity and product innovation. Considerable exemptions apply, esp. for patients suffering from chronic diseases (33 defined conditions are altogether exempt from paying the co-payment) these have a 0% co-payment; approximately 83% of prescriptions are free of copayment; most other drugs carry the 35% co-payment, whereas the 65% applies to most 'comfort drugs'; the majority of French citizens have additional insurance that covers (most of) these co-payments

Germany Fixed co-payments based on pack size

- 25% per prescription item applies to all patients with the exception of those suffering from chronic and/or life-threatening illnesses; the co-payment rate is uniform across all sickness funds
- 0% of 10% co-payment for patients suffering from chronic or lifethreatening illnesses

Abolished as of 1 January 2001 in preparation for the reference pricing system; patient will only pay if he opts for a more expensive medication than the reference one

None other than patients paying any excess over the reference price if they choose the non-reference product

- Patients pay out-of-pocket between 31-35% of total pharmaceutical costs;
- Reimbursement is reserved mainly for chronic conditions
- For medicines admitted to the positive list the co-payment rates are 0% (for patients under the age of 7 years), 12% with a limit of NKr 150 per script (for children up to age 16 and elderly patients over 67), and 30% for al other patients with a limit of NKr330 per script
- Co-payments are of the percentage type: 4 reimbursement categories (A, B, C, D) exist: 0%, 30%, 60% 80%; classification in categories is done as in 1999; a new category (Group D was introduced recently comprising categories of comfort medicines)
- The above co-payments are 10% lower if a generic is dispensed: 0%, 20%, 50%, 70%
- For pensioners the reimbursement levels for branded products are 15% lower: 0%, 15%, 45%, 65%

France

Denmark

Greece

Italy

Netherlands

Norway

Portugal

Three co-payment rates:

- Spain
- a. 40% of retail price applies to the active population and its dependents;
 b. reduced rate of 10% of retail price for drugs in therapeutic categories for certain chronic conditions (eg insulin, anti-cancer preparations, human growth hormones, and since 1995, HIV-related infections); Up to a maximum of PTA 439 per item;
- c. 0% for pensioners and certain categories of invalids.
- Payment by instalments permitted (not more than SEK 150 per month)
- Under the new reimbursement system, a deductible plus a fixed fee per item are proposed as follows:

Sweden

• The deductible is set at SEK 1,800 per annum; however, the cost of prescriptions for children under 18 within a family – which may be added together – would be reduced to SEK 900. Once the SEK 1,800 level has been attained, a flat fee of SEK 40 per item applies, up to a total of SEK 1,000 (25 items) per annum

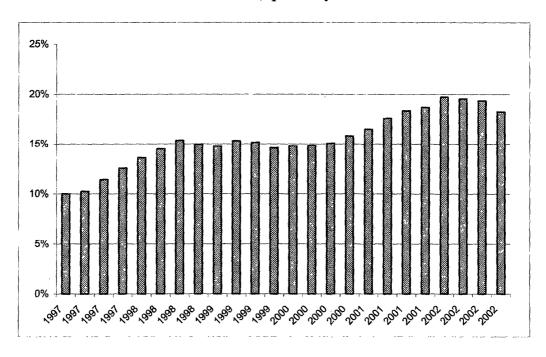
UK

Flat fee per prescription item: UK£6.30 as of 1 April 2003; 4-month pre-payment certificate: £32.90; 12-month pre-payment certificate: £90.40

Source:

P. Kanavos, 2003.

Figure 5.1 Market Share of Parallel Imports in 5 EU countries¹ and Norway; 1997-2002, quarterly data²



¹ The EU countries included here are: Denmark, Germany, the

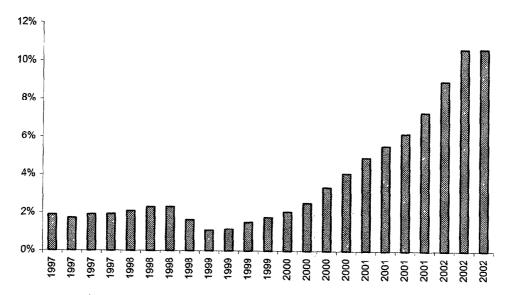
Netherlands, Sweden, and the UK.

² Parallel import sales from 19 high-volume products, selected across 6 product categories and expressed as a proportion of total sales for these products.

Source:

Authors' compilations from IMS.

Figure 5.2 Aggregate market share of parallel imports in Germany, 1997-2002¹



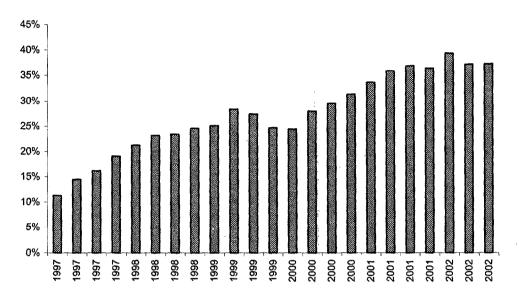
¹ Parallel import sales from 19 high-volume products, selected across 6 product categories and expressed as a proportion of total sales for these

products.

Source:

Authors' compilations from IMS.

Figure 5.3
Aggregate market share of parallel imports in the UK, 1997-2002¹

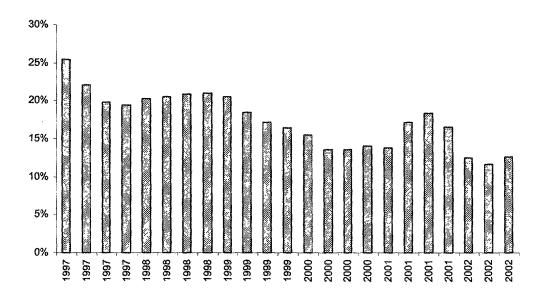


¹ Parallel import sales from 19 high-volume products, selected across 6 product categories and expressed as a proportion of total sales for these products.

Source:

Authors' compilations from IMS.

Figure 5.4 Aggregate market share of parallel imports in the Netherlands, 1997-2002¹



¹ Parallel import sales from 19 high-volume products, selected across 6 product categories and expressed as a proportion of total sales for these products.

produci

Source: Authors' compilations from IMS.

Table 5.1

Aggregate PI market share per product in 6 importing countries¹,
1997 – 2002, (individual product parallel import sales in 6 countries as a proportion of the same product's total sales in the same countries)

PIUPULUUM UL L			O COCK 1346EC13	**************************************	MILL CURREN	1100)
Product	1997	1998	1999	2000	2001	2002
Atorvastatin	0%	0%	2%	22%	18%	19%
Pravastatin	6%	9%	14%	17%	20%	19%
Simvastatin	14%	16%	21%	29%	33%	33%
Captopril	2%	2%	2%	1%	1%	2%
Enalapril	9%	11%	12%	4%	2%	1%
Quinapril	2%	3%	3%	4%	9%	16%
Ramipril	1%	2%	2%	3%	2%	3%
Losartan	0%	6%	12%	18%	23%	25%
Valsartan	0%	0%	1%	3%	9%	11%
Clozapine	18%	18%	19%	20%	22%	24%
Olanzapine	0%	0%	0%	6%	15%	27%
Risperidone	21%	30%	37%	42%	47%	53%
Lansoprazole	14%	22%	18%	15%	26%	28%
Omeprazole	27%	21%	15%	9%	9%	4%
Pantoprazole	1%	2%	5%	6%	9%	11%
Citalopram	5%	7%	9%	10%	17%	19%
Fluoxetine	23%	35%	35%	19%	13%	10%
Paroxetine	10%	17%	20%	22%	23%	15%
Sertraline	5%	6%	11%	10%	15%	17%

¹ The countries included here are: Denmark, Germany, the

Netherlands, Norway, Sweden, and the UK.

Source:

Authors' calculations from IMS data.

Table 5.2
Market shares of selected PI products. 2002

	Market S	nares of se	iected Pi	products,	2UU2	
Product	Norway	Germany	Sweden	Denmark	UK	Netherlands
Atorvastatin	2%	0%	17%	5%	54%	12%
Pravastatin	14%	1%	19%	0%	38%	7%
Simvastatin	36%	9%	0%	56%	65%	51%
Captropril	3%	1%	0%	7%	2%	0%
Enalapril	24%	0%	19%	5%	4%	1%
Quinapril	0%	8%	0%	39%	8%	17%
Ramipril	0%	3%	18%	19%	0%	21%
Losartan	0%	0%	0%	0%	72%	0%
Valsartan	0%	5%	0%	0%	23%	20%
Clozapine	58%	0%	74%	13%	0%	10%
Olanzapine	11%	63%	24%	0%	47%	8%
Risperidone	42%	62%	32%	25%	45%	33%
Lansoprazole	0%	42%	0%	0%	31%	14%
Omeprazole	4%	0%	16%	0%	19%	11%
Pantoprazole	0%	6%	0%	0%	32%	18%
Citalopram	6%	17%	21%	19%	25%	15%
Fluoxetine	1%	5%	20%	17%	10%	34%
Paroxetine	9%	19%	47%	43%	18%	6%
Sertraline	0%	9%	8%	25%	23%	14%

Source: Authors' calculations from IMS.

Table 6.1

	Denmark: The economic impact of pharmaceutical parallel trade, 2002 Oduct name Sales 2002 Individual PI Average Savings Savings Maximum Maximum profit										
			PI	Average	Savings	Savings	Maximum	Maximum profit			
	(in € 000 at		market	price	accruing	as		accruing			
	PPP level)1		shares	spread	to	% of	to parallel	to parallel			
		of all		between	health	total	importers	importers			
		19		locally-			(taking the	(taking the			
		product sales ²		and PI- sourced	(in € 000 at PPP	market		average of the 3			
		Saics	}		level)4		level) ⁵	lowest EU prices in € 000 at PPP) ⁵			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)			
Atorvastatin	€12,502	9%	5%	26%	€ 207	1.7%	€ 242	€ 158			
Pravastatin*	€6012	4%	0%	0%	€0	0.0%	€0	€0			
Simvastatin	€21,600	16%	56%	6%	€ 1,080	5.0%	€ 3,960	€ 3,807			
Captopril	€249	0%	7%	30%	€ 0.24	0.1%	€ 3.2	€ 2.5			
Enalapril	€130	0%	5%	30%	€ 0.26	0.2%	€ 56	€ 20.5			
Quinapril	€360	0%	39%	4%	€ 5.1	1.4%	€ 76	€ 46.8			
Ramipril	€6,420	5%	19%	22.6%	€ 104	1.6%	€ 223	€ 120.7			
Losartan	€8,886	6%	0%	0%	€0	0.0%	€0	€0			
Valsartan	€1,475	1%	0%	0%	€0	0.0%	€0	€0			
Clozapine	€1,380	1%	13%	6%	€11	0.8%	€ 94	€ 64.4			
Olanzapine	€4,800	3%	0%	0%	€0	0.0%	€0	€0			
Risperidone	€5,410	4%	25%	38%	€ 29	0.5%	€ 310	€ 117.8			
Lansoprazole	€7,205	5%	0%	0%	€0	0.0%	€0	€0			
Omeprazole	€23,130	17%	0%	0%	€0	0.0%	€0	€0			
Pantoprazole	€4218	3%	0%	0%	€0	0.0%	€0	€0			
Citalopram	€15,740	11%	19%	6.6%	€ 173	1.1%	€ 1,545	€ 1,134.3			
Fluoxetine	€2,270	2%	17%	14%	€ 20.7	0.9%	€ 315	€ 308.1			
Paroxetine	€3,860	3%	43%	26%	€ 165	4.3%	€ 305	€ 90.3			
Sertraline	€13,070	9%	25%	19%	€ 1,207	9.2%	€ 242	€ 156.9			
TOTAL	€138,717	100%	28.1% ⁷	8.4%8	€3,002	2.2%	€7,371.2	€6,027.3			

Notes: 1 Sales 2002 in thousand EURO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

Source: Authors' compilations from IMS.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, the applicable retail margins and VAR need to be added.

³ Weighted average price spread (at PPP level) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

Savings accruing to health insurance (in '000 EURO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

Maximum profit accruing to parallel importers (in €URO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average PI market share, based on sales 2002 is 17.5%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

Total savings as % of total product market: Weighted average savings, based on sales 2002.

^{*}For pravastatin there may be parallel trade but because non of the formulation in the countries examined are similar to those in the Danish market we did not re-calculate on the basis of adjusting for dosage.

Table 6.2 Savings of the product with the highest market penetration in Denmark (Simvastatin); in € '000'; 2002

	q ^{PI} (packs)	€ P ^{PI 1}	€ P ^{orng 1}	Savings¹ '000'€
TABL F'OVT 10MG 28	29,707	€24	€26	€58.1
TABL F'OVT 10MG 98	45,914	€82	€89	€326.2
TABL F'OVT 20MG 28	37,736	€35	€38	€113.2
TABL F'OVT 20MG 98	54,236	€118	€129	€601.5
TABL F'OVT 40MG 28	2,023	€48	€50	€4.3
TABL F'OVT 40MG 98	53	€118	€168	€2.6
TABL F'OVT 80MG 28	0	€0	€53	€0
TABL F'OVT 80MG 98	0	€0	€182	€0

Note: ¹ At PPP level.

Source: Authors' compilation from IMS.

Table 6.3

Geri	nany: 1 ne	economi	c impa			ical pai	rallel trade, 20	U2
Product name	Sales 2002 (in € 000 at PPP level) ¹	Individual product sales as % of all 19 product sales ²	PI market shares	price spread between locally- and PI- sourced	Savings accruing to health insurance (in € 000 at PPP level) ⁴	Savings as % of total product market	Maximum profit accruing to parallel importers (taking the lowest EU price in € 000 at PPP level) ⁵	Maximum profit accruing to parallel importers (average of the 3 lowest EU prices in € 000 at PPP level) ⁵
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Atorvastatin	€ 411,000	19%	0%	0%6	€0	0.00%	€0	€0
Pravastatin	€ 116,000	5%	0.3%	9%	€ 44	0.25%	€ 99	€77
Simvastatin	€ 248,000	11%	9%	5%	€ 1,125	6.35%	€ 15,067	€ 10,787
Captopril	€ 61,700	3%	8%	8%	€ 84	0.47%	€ 793	€ 556
Enalapril	€ 146,600	7%	0.4%	13%	€7	0.04%	€ 44	€ 20
Quinapril	€ 12,200	1%	11%	6%	€ 85	0.48%	€ 346	€ 265
Ramipril	€ 117,800	5%	5%	9%	€ 98	0.55%	€ 486	€ 268
Losartan	€ 46,400	2%	0%	0%6	€0	0.00%	€0	€0
Valsartan	€ 62,300	3%	5%	5%	€ 149	0.84%	€ 646	€ 445
Clozapine	€ 20,600	1%	0%	0% ⁶	€0	0.00%	€0	€0
Olanzapine	€ 117,700	5%	62%	6%	€ 4,058	22.89%	€ 31,513	€ 24,846
Risperidone	€ 85,900	4%	62%	10%	€ 5,569	31.41%	€ 25,718	€ 21,265
Lansoprazole	€ 37,700	2%	39%	11%	€ 2,361	13.32%	€ 7,311	€ 6,499
Omeprazole	€ 350,000	16%	0.2%	8%	€ 46	0.26%	€ 38	€19
Pantoprazole	€ 206,400	9%	6%	11%	€ 1,451	8.18%	€ 5,586	€ 5,498
Citalopram	€ 69,700	3%	28%	6%	€ 854	4.82%	€ 5,360	€ 5,246
Fluoxetine	€ 22,200	1%	37%	21%	€ 481	2.71%	€ 1,621	€ 1,419
Paroxetine	€ 34,300	2%	30%	15%	€ 1,187	6.69%	€ 2,491	€ 1,927
Sertraline	€ 41,800	2%	7%	5%	€ 121	0.68%	€ 1,281	€ 980
TOTAL	€ 2,208,300	100%	13.5% ⁷	6.7%8	€ 17,730	0.8%9	€ 97,965	€80,309

Notes: 1 Sales 2002 in thousand €URO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

Source: Authors' compilations from IMS.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, all figures need to be multiplied by 1.508 (comprising retail margin and VAT in Germany).

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

⁴ Savings accruing to health insurance (in '000 €URO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

Maximum profit accruing to parallel importers (in EURO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average of PI market share, based on sales 2002 is 11%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

Total savings as % of total product market: Weighted average savings, based on 2002 sales.

Table 6.4
Savings of the product with the highest market penetration in Germany (Risperidone); in € '000', 2002

	q ^{PI} (packs)	$\in P^{PI}$	€ P ^{orig}	Savings ¹
FILMTABL .5MG 20	1,784	€14	€16	€ 3.8
FILMTABL .5MG 50	0	€0	€9	€0
FILMTABL 1MG 100	47,968	€102	N/A	€0
FILMTABL 1MG 20	58,491	€19	€22	€ 175.5
FILMTABL 1MG 50	516	€52	€58	€ 3.1
FILMTABL 2MG 100	30,154	€200	€219	€ 573
FILMTABL 2MG 20	166,83	€41	€45	€ 667.3
FILMTABL 2MG 50	122,072	€99	€111	€ 1,464.8
FILMTABL 3MG 100	11,973	€291	€324	€ 395.1
FILMTABL 3MG 20	17,216	€57	€67	€ 172.2
FILMTABL 3MG 50	41,777	€147	€164	€ 710.2
FILMTABL 4MG 100	6,270	€387	€430	€ 269.6
FILMTABL 4MG 20	3,039	€79	€88	€ 9.1
FILMTABL 4MG 50	24,878	€194	€216	€ 547.3
LOESG 1MG/ML 100ML	33,082	€112	€125	€ 430.1
LOESG 1MG/ML 30ML	47,772	€35	€40	€ 238.9
PULV CONSTA 25MG 2ML	0	0	€60	€0
PULV CONSTA 37.5MG 2ML	0	0	€90	€0
PULV CONSTA 50MG 2ML	0	0	€120	€0
TAB.QUICKLET 1MG 28	0	0	€17	€0
TAB.QUICKLET 1MG 56	0	0	€37	€0
TAB.QUICKLET 2MG 28	0	0	€37	€0
TAB.QUICKLET 2MG 56	0	0	€73	€0

Note: ¹In '000'€ at PPP level.

Source: Authors' compilations from IMS.

The Economic Impact of Pharmaceutical Parallel Trade

Discussion Paper

Table 6.5
The Netherlands: The economic impact of pharmaceutical parallel trade, 2002

Dyoduot nome	Sales 2002	.,		A	¥72.21.1.	X72	/T-4-T	G ·	Ticai paranei i	T70 *2 2 3 #2 *		55 50
	Sales 2002 (in € 000 at PPP level) ¹	1	shares	Average price spread between locally-and PI-sourced products ³	accruing to health insurance	Visible Savings as % of total product market	savings (incl. claw- back) accruing to	total	profit accruing to parallel importers (taking the lowest EU price in € 000 at PPP level) ⁵	average of the 3 lowest EU prices	profit accruing to parallel importers (taking the lowest EU price in € 000 at PPP	Maximum profit accruing to parallel importers (taking the average of the 3 lowest EU prices in € 000 at PPP) ⁵
				products			PPP level) ⁴			me ood at FIF)	level)	in cood at FFF)
(1)	(2)	(3)	(4)	(5)	(6)	(6b)	(7)	(7b)	(8)	(9)	(10)	(11)
Atorvastatin	€84,100	16%	12%	6%	€ 2,390	2.8%	€2,920	3.5%	€4,325	€2,581	€3795	€1866
Pravastatin	€46,900	9%	7%	12%	€118.2	0.3%	€349	0.7%	€986	€691	€755.2	€532
Simvastatin	€89,000	17%	51%	22%	€ 5,075	5.7%	€8,075	9.1%	€24,810	€19,983	€21,810	€18,837
Captopril	€380	0%	0%	0%	€0	0.0%	€0	0.0%	€0	€0	€0	€0
Enalapril	€6,300	1%	1%	17%	€11.4	0.2%	€17	0.3%	€33.9	€24	€28.3	€23.4
Quinapril	€6,110	1%	17%	12%	€ 326	5.3%	€401	6.6%	€595.4	€430	€520.3	€327
Ramipril	€5,711	1%	21%	6%	€ 145	2.5%	€221	3.9%	€627.2	€579	€551	€537
Losartan	€25,000	5%	0%	23%	€ 4.9	0.0%	€10	0.0%	€20.9	€16	€15.8	€14.2
Valsartan	€10,000	2%	20%	13%	€.99	1.0%	€139	1.4%	€830.6	€ 676	€680.2	€572
Clozapine	€1,281	0%	10%	8%	€ 7.3	0.6%	€17	1.3%	€75.3	€62	€65.6	€55.6
Olanzapine	€20,295	4%	8%	15%	€ 95.1	0.5%	€215	1.1%	€528.9	€399	€409	€324
Risperidone	€11,030	2%	33%	7%	€ 321.2	2.9%	€593	5.4%	€1,949.8	€1,629	€1,678	€1156
Lansoprazole	€10,760	2%	14%	11%	€ 68	0.6%	€159	1.5%	€824.9	€787	€734	€569
Omeprazole	€133,075	25%	11%	18%	€ 3,070	2.3%	€4,228	3.2%	€9,642	€6,851	€8,484	€5963
Pantoprazole	€32,970	6%	18%	25%	€ 605	1.8%	€1,047	3.2%	€2,403	€2,047	€1961	€1593
Citalopram	€7,000	1%	15%	12%	€ 86	1.2%	€160	2.3%	€614.1	€522	€540	€487
Fluoxetine	€3,100	1%	34%	11%	€ 173	5.6%	€250	8.1%	€437.3	€303	€360	€238
Paroxetine	€23,260	4%	6%	18%	€ 61	0.3%	€119	0.5%	€303.3	€246	€245	€181
Sertraline	€8,590	2%	14%	10%	€ 107	1.2%	€199	2.3%	€659.3	€498	€567	€456
TOTAL	€524,862	100%	19% ⁷	15.8% ⁸	€ 12,762	2.2%	€19,119	3.6%	€49,666.9	€38,324	€43,199.4	€33,731.2

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Notes: ¹ Sales 2002 in thousand EURO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, the applicable retail margins and VAT need to be added.

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

Source: Authors' compilations from IMS.

⁴ Savings accruing to health insurance (in '000 EURO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

⁵ Maximum profit accruing to parallel importers (in €URO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average PI market share, based on sales 2002 is 18%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

⁹ Total savings as % of total product market: Weighted average savings, based on sales 2002.

Table 6.6 Savings of the product with the highest market penetration in the Netherlands (Simvastatin); in € '000', 2002

	q ^{PI} (packs)	€ P ^{P/ 1}	€ P ^{orig 1}	Savings¹ '000'€
TABL 10MG 30 STRP		€0.0	€37.8	-
TABL 10MG 5 X10	-	€0.0	€62.9	→
TABL 20MG 30 STRP	509,967	€38.6	€44.3	€1,869
TABL 20MG 5 X10	-	€0.0	€73.5	-
TABL 40MG 30	443,064	€55.1	€62.4	€3,205
TABL 40MG 50 STR0	····	€0.0	€103.3	***************************************

Note: ¹In '000'€ at PPP level.
Source: Authors' compilations from IMS.

Table 6.7-1

Origin of total parallel imported sales to the Netherlands (Simvastatin)

AND ASSESSMENT OF THE PROPERTY	eabtitectures and frequency and a second and a	F4440000000000000000000000000000000000	***************************************	***************************************
	1998	2000	2002	Relative price
Greece	0.0%	0.9%	2.1%	0.71
UK	0.0%	6.5%	3.7%	0.92
Italy	3.3%	1.3%	0.0%	0.74
France	82.6%	80.4%	67.7%	0.74
Portugal	0.0%	0.4%	0.0%	0.85
Spain	14.1%	10.5%	26.4%	0.54

Table 6.7-2

Origin of parallel imported sales to the Netherlands by presentation (Simvastatin)

44444444444	Greece	UK	Italy	France	Spain	Portugal	Total PI sales	Present.1	Locally sourced sales	PI % ²
*******************************					1998	}				,
1 0mg	0	0	0	0	672	0	672	2%	39703	2%
20 mg	0	0	900	22,411	2383	0	25694	95%	16693	61%
40mg	0	0	0	0	778	0	778	3%	5059	13%
					2000					
10mg	0	0	0	0	32	0	32	0%	330	9%
20 mg	405	2,935	583	36,024	1356	160	41463	93%	29938	58%
40mg	0	_0	0	0	3329	0	3329	7%	8767	28%
					2002					
10mg	0	0	0	0	33	0	33	0%	339	9%
20 mg	705	1,227	0	21,777	2397	0	26106	79%	52740	33%
40mg	0	00	0	455	6260	0	6715	20%	13491	33%

16/00f each presentation in total sales.
 20/00f parallel imported sales per presentation.

Table 6.7-3

Origin of total parallel imported sales to the Netherlands (Fluoxetine)

	\$	######################################	on a succession of the success	**************************************
***************************************	1998	2000	2002	Relative price
France	99%	71%	32%	0.96
Spain	1%	29%	68%	0.77

Table 6.7-4
Origin of total parallel imported fluoxetine to the Netherlands by presentation

### ##################################	н иовинеского посторова			ocally sourced	00000000000000000000000000000000000000
	France	Spain	PI sales	sales	% PI
1998 (20mg)	7989	90	8079	8083	50%
2000 (20 mg)	1343	554	1897	4258	31%
2002 (20mg)	354	769	1123	4449	20%

Table 6.7-5

Origin of total parallel imported risperidone to the Netherlands

	1998	2000	2002	Relative prices
Greece	0%	0%	1%	0.56
Italy	51%	39%	45%	0.77
France	49%	61%	52%	0.69
Spain	0%	0%	2%	0.68

*Relative prices of matched presentation from each exporting country.

Table 6.7-6
Origin of parallel imported risperidone to the Netherlands by presentation

	Greece	Italy	France	Spain	Total	Percent	Original	PI %
1mg	0	106	102	0	208	100%	2140	9%
2mg	0	0	-	0	0	0%	1354	0%
3mg	0	0	0	0	0	0%	852	0%
4mg	0	0	0	0	0	0%	690	0%
Total 1998	0	106	102	0	208	100%	5036	4%
1mg	0	783	523	0	1306	65%	2078	39%
2mg	0	0	667	0	667	33%	2189	23%
3mg	0	10	-	0	10	0%	1534	1%
4mg	0	0	26	0	26	1%	1244	2%
Total 2000	0	793	1216	0	2009	1000	7045	22%
1mg	0	1167	239	61	1467	41%	3250	31%
2mg	0	0	1,166	0	1166	33%	2140	35%
3mg	34	447	0	0	481	13%	1376	26%
4mg	0	0	450	0	450	13%	1165	28%
Total 2002	34	1614	1855	61	3564	100%	7931	31%

Table 6.8

Norway: The economic impact of pharmaceutical parallel trade, 2002

Norway: The economic impact of pharmaceutical parallel trade, 2002									
		Individual					Maximum	Maximum profit	
	(in € 000 at			price	accruing	as	profit accruing accruing		
	PPP level)1	sales as %	1	spread	to	% of	to parallel	to parallel	
		of all 19 product		between locally-	health insurance	total product	importers (taking the	importers (taking the	
		sales ²		and PI-	(in € 000	market	lowest EU	average of the 3	
		Saics	1	sourced	at PPP	III III	price in € 000	lowest EU prices	
					level)4		at PPP level) ⁵	in € 000 at PPP) ⁵	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
Atorvastatin	€ 9,900	5%	2%	6%	€10	0.1%	€437.3	€198.5	
Pravastatin	€ 16,500	8%	14%	2%	€28	0.2%	€596.6	€436.6	
Simvastatin	€ 53,900	27%	36%	1%	€106	0.2%	€8,114.8	€4,842.9	
Captopril	€700	0.4%	3%	2%	€0,5	0.1%	€28.8	€21.9	
Enalapril	€ 5,100	3%	24%	25%	€212	4.2%	€170	€69.4	
Ramipril	€ 6,800	3%	0%	1%	€0.21	0.0%	€28.12	€14.1	
Losartan	€9816	5%	0%	0%	€0	0%	€0	€0	
Valsartan	€218	0.1%	0%	0%	€0	0%	€0	€0	
Clozapine	€1,100	1%	58%	4%	€21.4	1.9%	€182	€123.8	
Olanzapine	€14,400	7%	11%	1%	€12.3	0.1%	€394	€378.3	
Risperidone	€4,100	2%	42%	1%	€110	2.7%	€241	€149.1	
Lansoprazole	€10,900	6%	0%	0%	€0	0%	€0	€0	
Omeprazole	€15,200	8%	4%	1%	€8.2	0.1%	€663.7	€397.4	
Pantoprazole	€474	0.2%	0%	0%	€0	0.0%	€0	€0	
Citalopram	€22,500	11%	6%	1%	€15.1	0.1%	€656.6	€360	
Fluoxetine	€2,300	1%	1%	39%	€5.5	0.2%	€6.8	€6.4	
Paroxetine	€11,400	6%	9%	1%	€34.3	0.3%	€928.2	€471.4	
Sertraline	€11,100	6%	0%	0%	€0	0%	€0	€0	
TOTAL	€196,408	100%	18.3% ⁷	2.5%8	€563.1	0.3%	€12,447	€7,470	

Notes: ¹ Sales 2002 in €URO thousand at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, the relevant retail margins and VAR need to be added on.

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

⁴ Savings accruing to health insurance (in '000 €URO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

⁵ Maximum profit accruing to parallel importers (in EURO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average PI market share, based on sales 2002 is 18.3%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

⁹ Total savings as % of total product market: Weighted average savings, based on sales 2002.

⁹ Total savings as % of total product market: Weighted average savings, based on sales 2002. *Source:* Authors' compilations from IMS.

Table 6.9

Savings accruing to health insurance from the product with the highest market penetration in Norway (Clozapine); in € '000', 2002

	qPI (packs)	$oldsymbol{\epsilon}_{P^{PI}}$	$\mathbf{\epsilon}_{P^{orig}}$	Savings ¹
TAB 100MG 100	8,775	60.8	63.3	21.4
TAB 25MG 100	0	0	18.3	0

Note: ¹In '000'€ at PPP level.

Table 6.10
Sweden: The economic impact of pharmaceutical parallel trade, 2002

	Sweden: The economic impact of pharmaceutical parallel trade, 2002									
Product name	Sales 2002	Individual	PI	Average	Savings	Savings	Maximum profit	Maximum profit		
	(in € 000 at	product	market	<u> </u>	accruing to		accruing	accruing		
	PPP level) ¹	sales as %	shares	spread	health	% of	to parallel	to parallel		
		of all		(at PPP)		total	importers	importers		
		19 product		between	(in € 000 at		(taking the	(taking the		
		sales ²		locally- and PI-	PPP level)4	market	lowest EU price in € 000 at PPP	average of the 3 lowest EU prices		
				sourced			level) ⁵	in € 000 at PPP		
				products ³				level) ⁵		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)		
Atorvastatin	€ 33,870	9.6%	17%	12%	€ 251	0.7%	€ 1,258	€ 754		
Pravastatin	€ 13,460	3.8%	19%	6%	€ 172	1.3%	€ 847	€ 509		
Simvastatin	€74,200	21%	0%	0%	€0	0.0%	€0	€0		
Captopril	€745	0.2%	0%	0%	€0	0.0%	€0	€0		
Enalapril	€ 2,450	0.7%	19%	4%	€ 26	1.1%	€ 368	€ 260.8		
Quinapril	€385	0.1%	0%	0%	€0	0.0%	€0	€0		
Ramipril	€ 14,730	5%	18%	14%	€ 372	2.5%	€ 493	€ 304.9		
Losartan	€14,072	4.2%	0%	0%	€0	0.0%	€0	€0		
Valsartan	€3,468	1%	0%	0%	€0	0.0%	€0	€0		
Clozapine	€ 1,230	0.3%	74%	17%	€ 256	19.5%	€ 632.3	€ 461.2		
Olanzapine	€ 12,200	3.4%	24%	13%	€414	3.4%	€ 2,261	€ 1,881.7		
Risperidone	€ 11,150	3.1%	32%	14%	€ 543	4.9%	€ 3,090	€ 3,334.4		
Lansoprazole	€37,420	10.6%	0%	0%	€0	0.0%	€0	€0		
Omeprazole	€ 58,000	16.4%	16%	19%	€ 538	0.9%	€ 500	€ 379.4		
Pantoprazole	€4,055	1.1%	0%	0%	€0	0.0%	€0	€0		
Citalopram	€ 32,700	9.3%	21%	7%	€ 104	0.3%	€ 1,680.3	€ 1,464		
Fluoxetine	€ 3,600	1%	20%	18%	€ 165	4.6%	€ 353.6	€ 578.9		
Paroxetine	€ 8,430	2.4%	47%	8%	€ 44	0.5%	€ 4,993	€ 4,859.2		
Sertraline	€ 27,500	7.8%	8%	10%	€ 887	3.2%	€ 1,983	€ 1,956.8		
TOTAL	€ 353,665	100%	31%7	2.2%8	€ 3,770	1.3%	€ 18,453	€16,744		

Notes: ¹ Sales 2002 in thousand €URO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, the relevant retail margins and VAT need to be added on.

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

⁴ Savings accruing to health insurance (in '000 €URO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

⁵ Maximum profit accruing to parallel importers (in EURO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average PI market share, based on sales 2002 is 15%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

spread, based on sales 2002.

Total savings as % of total product market: Weighted average savings, based on sales 2002.

Source: Authors' compilations from IMS.

Table 6.11 Savings accruing to health insurance from the product with the highest market penetration in Sweden (Clozapine); in ϵ '000', 2002

				007220007070707070707070707070707070707
	q ^{PI} (packs)	$ \in P^{PI} $ in PPP	$ \in P^{orig} $ in PPP	Savings ¹
TAB GL 100MG 100	17,198	€70	€84	€237.3
TABL 25MG 100	4,726	€18	€22	€18.5

Note: ¹In '000'€ at PPP level.

Table 6.12 United Kingdom: The economic impact of pharmaceutical parallel trade, 2002

				.UUZ	· · · · · · · · · · · · · · · · · · ·		·	
Product name	Sales 2002 (in € 000 at PPP level) ¹	Individual product sales as % of all 19 product sales ²	market	Average price spread between locally-and PI-sourced products ³	to health insurance	as % of total product	Maximum profit accruing to parallel importers (taking the lowest EU price in € 000 at PPP level) ⁵	Maximum profit accruing to parallel importers (taking the average of the 3 lowest EU prices in € 000 at PPP) ⁵
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Atorvastatin	€296,000	15%	54%	0%	€0	0%	€82,711	€57,242
Pravastatin	€135,000	7%	38%	0%	€2	0%	€33,972	€30,665
Simvastatin	€501,000	25%	65%	0%	€0	0%	€231,132	€187,071
Captopril	€12,000	0.6%	2%	0%	€0	0%	€180	€128
Enalapril	€5,000	0.3%	4%	0%	€0	0%	€114	€81
Quinapril	€6,000	0.3%	8%	0%	€0	0%	€442	€387
Ramipril	€6900	0.3%	0%	0%	€0	0%	€0	€0
Losartan	€83,000	4.2%	72%	0%	€0	0%	€28,078	€24,194
Valsartan	€31,000	1.6%	23%	0%	€0	0%	€3,754	€2,701
Clozapine	€1373	0.1%	0%	0%	€0	0%	€0	€0
Olanzapine	€125,000	6.3%	47%	0%	€0	0%	€28,802	€24,927
Risperidone	€54,000	2.7%	45%	0%	€0	0%	€14,789	€12,836
Lansoprazole	€258,000	13.1%	31%	0%	€0	0%	€31,140	€21,072
Omeprazole	€175,000	8.9%	19%	0%	€0	0%	€29,408	€26,549
Pantoprazole	€25,000	1.3%	32%	0%	€0	0%	€2,913	€1,945
Citalopram	€94,000	4.8%	25%	0%	€0	0%	€13,630	€10,950
Fluoxetine	€20,000	1.0%	10%	9%	€192	1%	€1,054	€830
Paroxetine	€81,000	4.1%	18%	34%	€6,693	8.3%	€9,625	€8,078
Sertraline	€63,000	3.2%	23%	0%	€0	0%	€6,268	€4,707
TOTAL	€1,972,273	100%	27.4% ⁷	2.2%8	€6,887	0.3%	€518,013	€414,363
Total w/clawback(*)	€1,972,273	100%	27.4%	2.2%	€55,887	2.8%	€469,013	€365,363

Notes: 1 Sales 2002 in '000 EURO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level.

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

⁴ Savings accruing to health insurance (in '000 EURO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

⁵ Maximum profit accruing to parallel importers (in EURO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales); the weighted average PI market share, based on sales 2002 is 43%.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price spread, based on sales 2002.

Total savings as % of total product market: Weighted average savings, based on sales 2002.

(*) Figures for the clawback are estimates. **Source**: Authors' compilations from IMS.

Table 6.13
Savings accruing to the NHS from the product with the highest market penetration in the UK (Losartan); in € '000', 2002

	##0920000000000000000000000000000000000			
	q ^{PI} (packs)	$\mathcal{E}_{P^{PI}}$ in PPP	$\mathcal{E}P^{orig}$ in PPP	Savings
TABL 50MG 28	2,554,696	€27.1	€27.1	€0

Note: ¹In '000'€ at PPP level.

Table 6.14 All countries: The economic impact of pharmaceutical parallel trade 2002

	countries: 1 no					parame	i traue, 200	<u> </u>
Product name	Sales 2002 (in £000 at PPP level) ¹	Individual product sales as % of all 19 product sales ²	market shares	Average price spread (at PPP) between locally-and PI-sourced products ³	health insurance (in € 000 at PPP	Savings as % of total product market	Maximum profit accruing to parallel importers (taking the lowest EU price in € 000 at PPP level) ⁵	Maximum profit accruing to parallel importers (as the average of the 3 lowest EU prices in € 000 at PPP) ⁵
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Atorvastatin	€847,372	16%	21%	6%	€3,050	0.3%	€88,973	€60,933.50
Pravastatin	€333,872	6%	18%	9%	€ 436	0.1%	€36,500	€32,378.60
Simvastatin	€987,700	17%	47%	7%	€9,158	0.8%	€283,083	€226,490.90
Captopril	€75,774	1.4%	7%	10%	€84	0.1%	€1,005	€708.40
Enalapril	€165,580	3.1%	2%	15%	€256	0.2%	€785	€475.70
Quinalapril	€25,055	0.5%	12%	6%	€241	1.0%	€1,459	€1,128.80
Ramipril	€158,361	3.0%	7%	6%	€706	0.4%	€1,857	€1,286.70
Losartan	€187,174	3.5%	39%	12%	€7	0.0%	€28,098	€24,210.00
Valsartan	€108,461	2.0%	12%	6%	€248	0.2%	€5,230	€3,822.00
Clozapine	€26,964	0.5%	7%	7%	€295	1.0%	€983	€711.40
Olanzapine	€294,395	5.5%	50%	9%	€4,627	1.6%	€63,498	€52,432.00
Risperidone	€171,590	3.2%	51%	12%	€8,510	3.8%	€46,097	€39,331.30
Lansoprazole	€361,985	6.8%	31%	7%	€2,493	0.7%	€39,275	€28,358.00
Omeprazole	€754,405	14.2%	8%	9%	€4,563	0.4%	€40,251	€34,195.80
Pantoprazole	€273,117	5.1%	10%	12%	€2,344	0.8%	€10,902	€9,490.00
Citalopram	€241,640	4.5%	23%	5%	€1,275	0.5%	€23,486	€19,676.30
Fluoxetine	€53,470	1.0%	23%	19%	€1,031	1.9%	€3,787	€3,445.40
Paroxetine	€162,250	3.0%	20%	17%	€8,216	5.0%	€18,645	€15,671.90
Sertraline	€165,060	3.1%	16%	9%	€2,376	1.4%	€10,433	€8,298.70
TOTAL	€5,394,225	100%	25% ⁷	8% ⁸	€44,714	0.8%	€703,916	€563,237

Notes: ¹ Sales 2002 in '000 €URO at PPP (Pharmacy Purchase Price) level: Sales in retail sector only (i.e. sales in hospital sector not included). For patent-expired molecules only sales of the original branded product are considered.

² Individual product sales as % of all 19 product sales: at Pharmacy Purchase Price level. In order to arrive at public price level, retail margins and VAT need to be added on.

³ Weighted average price spread (at PPP) between locally- and PI- sourced products: Average of the different presentations (formulation/pack size) and companies.

⁴ Savings accruing to health insurance (in '000 EURO at PPP level): These savings include savings accruing from the direct financial impact (price differences) between locally sourced original and parallel imported equivalent.

⁵ Maximum profit accruing to parallel importers (in €URO at PPP level): Profit at lowest Pharmacy Purchase Price in potential export countries. The most common countries likely to be parallel exporters were Greece, Spain, Italy, Portugal and France, without excluding the possibility of other countries featuring in that list.

⁶ N/A: No (parallel import) sales observed, or sales were negligible.

⁷ Total PI market shares (sales): Weighted average PI market share, based on sales 2002.

⁸ Total average price spread (at PPP) between locally- and PI- sourced products: Weighted average price

spread, based on sales 2002.

Total savings as % of total product market: Weighted average savings, based on sales 2002. Source: Authors' compilations from IMS.

Table 6.15 Overall Savings to Health Insurance Organisations (in € 000), 2002

Product	Norway	Germany	Sweden	Denmark	UK^1		Netherlands ²
Atorvastatin	€10	€0	€ 251	€207	€0	€ 2,390	€2,920
Pravastatin	€28	€ 44	€ 172	€0	€2	€ 118.2	€349
Simvastatin	€106	€ 1,125	€0	€1,080	€0,	€ 5,075	€8,075
Captopril	€0,5	€ 84	€0	€0.24	€0	€0	€0
Enalapril	€212	€7	€ 26	€0.26	€0	€ 11.4	€17
Quinapril	N/a	€ 85	€0	€5.1	€0	€ 326	€401
Ramipril	0.21	€ 98	€ 372	€104	€0	€ 145	€221
Losartan	€0	€0	€0	€0	€0	€ 4.9	€10
Valsartan	€0	€ 149	€0	€0	€0	€ 99	€139
Clozapine	€21.4	€0	€ 256	€11	€0	€ 7.3	€17
Olanzapine	€12.3	€ 4,058	€414	€0	€0	€ 95.1	€215
Risperidone	€110	€ 5,569	€ 543	€29	€0	€ 321.2	€593
Lansoprazole	€0	€ 2,361	€0	€0	€0	€ 68	€159
Omeprazole	€8.2	€ 46	€ 538	€0	€0	€ 3,070	€4,228
Pantoprazole	€0	€ 1,451	€0	€0	€0	€ 605	€1,047
Citalopram	€15.1	€ 854	€ 104	€173	€0	€ 86	€160
Fluoxetine	€5.5	€ 481	€ 165	€20,7	€192	€ 173	€250
Paroxetine	€34.3	€ 1,187	€ 44	€165	€6,693	€ 61	€119
Sertraline	€0	€ 121	€ 887	€1,207	€0	€ 107	€199
Total		€ 17,730	€ 3,770	€3,002	€6,887	€ 12,762	€19,119

¹ Excludes the effect of the clawback in the UK and the Netherlands. An *estimate* for the clawback in the UK elevates savings to €55,887 million.
² Includes the effect of the clawback in the Netherlands.

Source:

From Tables 6.1, 6.3, 6.5, 6.7, 6.9, and 6.11.

Table 6.16
Visible savings to Health Insurance Organisations (% total market in pharmacy purchase prices - PPP), 2002

pharmacy purchase prices - PPP), 2002											
Product	Norway	Germany	Sweden	Denmark	UK^1	Netherlands ¹					
Atorvastatin	0.1%	0.00%	0.7%	1.7%	0%	3.5%					
Pravastatin	0.2%	0.25%	1.3%	0.0%	0%	0.4%					
Simvastatin	0.2%	6.35%	0.0%	5.0%	0%	7.7%					
Captopril	0.1%	0.47%	0.0%	0.1%	0%	0.0%					
Enalapril	4.2%	0.04%	1.1%	0.2%	0%	0.3%					
Quinalapril	N/A	0.48%	0.0%	1.4%	0%	6.6%					
Ramipril	0.0%	0.55%	2.5%	1.6%	0%	3.9%					
Losartan	0%	0.00%	0.0%	0,0%	0%	0.0%					
Valsartan	0%	0.84%	0.0%	0.0%	0%	1.4%					
Clozapine	1.9%	0.00%	19.5%	0.8%	0%	1.3%					
Olanzapine	0.1%	22.89%	3.4%	0.0%	0%	1.1%					
Risperidone	2.7%	31.41%	4.9%	0.5%	0%	5.4%					
Lansoprazole	0%	13.32%	0.0%	0.0%	0%	1.2%					
Omeprazole	0.1%	0.26%	0.9%	0.0%	0%	0.7%					
Pantoprazole	0.0%	8.18%	0.0%	0.0%	0%	12.8%					
Citalopram	0.1%	4.82%	0.3%	1.1%	0%	1.8%					
luoxetine	0.2%	2.71%	4.6%	0.9%	1%	8.1%					
Paroxetine	0.3%	6.69%	0.5%	4.3%	8.3%	0.4%					
Sertraline	0%	0.68%	3.2%	9.2%	0%	1.9%					
Fotal	0.3%	0.8%9	1.3%	2.2%	0.3%	2.2%					
Fotal				1	2.8%	3.6%					
w/clawback(*)		1 11 .1	1 1 00								

Note: 1

Does not include the clawback effect.

(*) For the UK these are estimates.

Table 6.17

Maximum profits accruing to parallel importers (in € 000), 2002

Product	Norway	Germany	Sweden	Denmark	UK ¹	Netherlands ¹	Netherlands ²
Atorvastatin	€437.3	€0	€ 1,258	€242	€82,711	€4,325	€3795
Pravastatin	€596.6	€ 99	€ 847	€0	€33,972	€986	€755.2
Simvastatin	€8114.8	€ 15,067	€0	€3,960	€231,132	€24,810	€21,810
Captopril	€28.8	€ 793	€0	€3.2	€180	€0	€0
Enalapril	€170	€ 44	€ 368	€56	€114	€33.9	€28.3
Quinalapril	N/a	€ 346	€0	€76	€442	€595.4	€520.3
Ramipril	€28.12	€ 486	€ 493	€223	€0	€627.2	€551
Losartan	€0	€0	€0	€0	€28,078	€20.9	€15.8
Valsartan	€0	€ 646	€0	€0	€3,754	€830.6	€680.2
Clozapine	€182	€0	€ 632.3	€94	€0	€75.3	€65.6
Olanzapine	€394	€31,513	€ 2,261	€0	€28,802	€528.9	€409
Risperidone	€241	€ 25,718	€ 3,090	€310	€14,789	€1,949.8	€1,678
Lansoprazole	€0	€ 7,311	€0	€0	€31,140	€824.9	€734
Omeprazole	€663.7	€38	€ 500	€0	€29,408	€9,642	€8,484
Pantoprazole	€0	€ 5,586	€0	€0	€2,913	€2,403	€1961
Citalopram	€656.6	€ 5,360	€ 1,680.3	€1,545	€13,630	€614.1	€540
Fluoxetine	€312	€ 1,621	€ 353.6	€315	€1,054	€437.3	€360
Paroxetine	€928.2	€ 2,491	€ 4,993	€305	€9,625	€303.3	€245
Sertraline	€0	€ 1,281	€ 1,983	€242	€6,268	€659.3	€567
Total	€12,757	€ 97,965	€ 18,453	€7,371.2	€518,013	€49,666.9	€43,199.4
Total w/clawback (*))			1	€469,013		

Note: 1 Excluding the effect of the clawback

(*) Takes into account the effect of the clawback in the UK (estimates only).

Source: The authors, based on IMS data.

Including the effect of the clawback. In the Netherlands, we have applied the 6.82% flat clawback on parallel trade sales.

N/A implies no parallel trade between countries, and, therefore, no benefits/costs accruing to/incurred by any of the stakeholders.

Table 6.18 Average mark-up of parallel importers in 2002

Product	Norway	Germany	Sweden	Denmark	UK1	Netherlands ¹	Netherlands
Atorvastatin	36%	0%	53%	10%	37%	27%	16%
Pravastatin	35%	23%	34%	0%	50%	25%	14%
Simvastatin	49%	71%	0%	36%	54%	55%	39%
Captopril	94%	92%	0%	49%	52%	0%	0%
Enalapril	16%	70%	80%	48%	46%	49%	34%
Quinalapril	0%	40%	0%	45%	69%	59%	42%
Ramipril	37%	56%	23%	22%	0%	53%	36%
Losartan	0%	0%	0%	0%	31%	31%	19%
Valsartan	0%	26%	0%	0%	36%	41%	27%
Clozapine	45%	N/a	69%	60%	0%	57%	41%
Olanzapine	28%	47%	76%	0%	34%	33%	21%
Risperidone	23%	60%	83%	25%	46%	53%	37%
Lansoprazole	0%	55%	0%	0%	21%	67%	49%
Omeprazole	57%	36%	6%	0%	72%	40%	34%
Pantoprazole	0%	57%	0%	0%	26%	61%	27%
Citalopram	54%	44%	52%	60%	52%	61%	44%
Fluoxetine	74%	42%	49%	97%	40%	42%	28%
Paroxetine	33%	40%	126%	22%	50%	39%	26%
Sertraline	0%	48%	93%	12%	28%	53%	37%
Average mark-up	46%	53%	60%	44%	54%	51%	44%
Average mark					400/		

w/clawback(*)

Notes:

49%

Excluding the clawback effect.

(*) Estimates for the clawback in the UK.

Source:

The authors, based on IMS.

Including the clawback effect.; in the Netherlands, we have applied the 6.82% discount which the Dutch government claws back from pharmacies.

Table 6.19

Profits accruing to Pharmacists (in € 000), 2002

	Norway	Germany	Sweden	Denmark	UK ¹	Netherlands
Atorvastatin	€10	0	0	0	0	€1,195
Pravastatin	€28	0	0	0	0	€59.1
Simvastatin	€106	0	0	0	0	€2,537
Captopril	€0,5	0	0	0	0	€0
Enalapril	€212	0	0	0	0	€5.7
Quinalapril	N/a	0	0	0	0	€163
Ramipril	€0.21	0	0	0	0	€72.5
Losartan	€0	0	0	0	0	€2.45
Valsartan	€0	0	0	0	0	€49.5
Clozapine	€21.4	0	0	0	0	€3.65
Olanzapine	€12.3	0	0	0	0	€47.55
Risperidone	€110	0	0	0	0	€160.6
Lansoprazole	€0	0	0	0	0	€34
Omeprazole	€8.2	0	0	0	0	€1,535
Pantoprazole	€0	0	0	0	0	€302
Citalopram	€15.1	0	0	0	0	€43
Fluoxetine	€5.5	0	0	0	0	€86
Paroxetine	€34.3	0	0	0	0	€30
Sertraline	€0	0	0	0	0	€53
Total	€563.1	0	0	0	0	€6,382

Includes the effect of visible price differences only.

Source:

The authors, based on IMS data.

Table 6.20 Maximum aggregate net benefits (19 products) from pharmaceutical parallel trade and their allocation between stakeholders (in thousand € 2000), 2002

	Norway	Germany	Sweden	Denmark	UK	Netherlands	All 6 countries
Total Sales at PPP € '000	€196,408	€ 2,208,300	€ 353,665	€138,717	€1,972,273	€524,862	€5,394,225
Total PI penetration (%)	18.3%	13.5%	31%	28.1%	27.4%	19%	25%
Total impact of PT¹€ '000	€13,573	€115,685	€22,223	€10,373	€524,900	€68,810	€755,564
Parallel importers maximum gross profits		€ 97,965	€ 18,453	€7,371.2	€518,013 (469,013) ²		
Parallel Importers Mark ups	46%	53%	60%	44%	54% (49%) ²	51% (44%) ²	53%
Health Service Savings	€563	€ 17,730	€ 3,770	€3,002	€6,887 (€55,887) ²	€12,762 (€19,119) ²	€44,714 (€100,071) ²
Savings % market	0.3%	0.8%	1.3%	2.2%	$0.3\%^3$ $(2.8\%)^2$	$\frac{2.2\%^3}{(3.6\%)^2}$	0.8% $(1.8\%)^2$
Pharmacists profits	€563	0	0	0	0	€6,382	€6,945
Pharmacies mark- up	2%	0%	0%	0%	0%	6%	0.6%
Patients	0	0	0	0	0	0	0
Ratio of profits/health insurance savings	22.66	5.53	4.89	2.46	75.22 (8.4) ²	4.01 $(2.26)^2$	16.01 $(6.48)^2$

¹ Or, equivalently, net loss to pharmaceutical manufacturers (producer loss).

² Including the effect of the clawback. In the UK these are estimates only.

³ This refers to savings without the clawback. If the clawback is included, the savings account for 2.4% of the branded prescription medicines market in the UK and 3.6% in the Netherlands. Source: Authors' compilations from IMS.

Table 6.21 Determinants of parallel trade

Model 1 (with exogenous prices)

Random-effects Group variable		i) : country		Number of obs Number of groups			1576 6
	= 0.1879 = 0.8109 = 0.2624			Obs per	group:	min = avg = max =	
Random effects corr(u_i, X)				Wald ch Prob >			558.06 0.0000
ParallelTrade		Std. Err.			[95%	Conf.	Interval]
Market size Exchange rate		.0404713	16.34		. 581	7811	.7404256
variability Distance	.1160944 .5848242	.0354165	3.28 3.17	0.001 0.002	. 046	5034	.1855095
sigma_u sigma_e rho	1.7825042	(fraction	of variar	ice due t	o u_i)		

Model 2 (with endogenous prices)

G2SLS Random-ef Group variable:			f obs =	_		
between	R-sq: within = 0.1433 between = 0.6017 overall = 0.2026					154 262.7 378
corr(u_i, X)	= 0 (ass	umed)		Wald chi Prob > c	_ (- /	488.09 0.0000
ParallelTrade	Coef.	Std. Err.	z	P> z	[95% Conf.	Interval]
Price gap Market size Exchange rate	3.162305 .6778305			0.002	1.182398 .591342	
variability	.2002261			0.000	-15.37266 .1542464 -4.715619	
sigma_u sigma_e rho	2.3725609	(fraction	of varian	ce due to	u_i)	
Instrumented: Instruments:	gap ls_t ppp ev	dist lgdp	 emu1			

Table 7.1

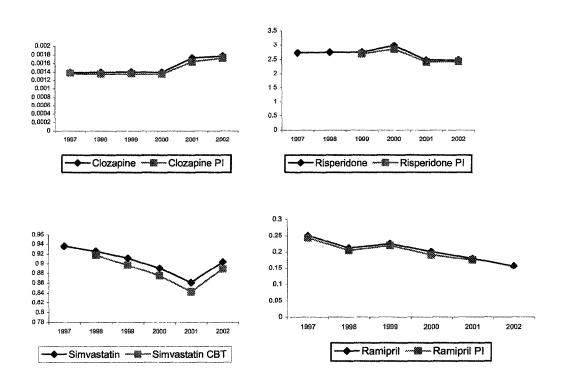
Average price spread between domestic and PI products (list or NHS prices in each study country), 2002

Product	Norway	Germany	Sweden	Denmark	UK	Netherlands
Atorvastatin	6%	0%	12%	26%	0%	6%
Pravastatin	2%	9%	6%	0%	0%	12%
Simvastatin	1%	5%	0%	6%	0%	22%
Captopril	2%	8%	0%	30%	0%	0%
Enalapril	25%	13%	4%	30%	0%	17%
Quinapril	0%	6%	0%	4%	0%	12%
Ramipril	1%	9%	14%	22.6%	0%	6%
Losartan	0%	0%	0%	0%	0%	23%
Valsartan	0%	5%	0%	0%	0%	13%
Clozapine	4%	0%	17%	6%	0%	8%
Olanzapine	1%	6%	13%	0%	0%	15%
Risperidone	1%	10%	14%	38%	0%	7%
Lansoprazole	0%	11%	0%	0%	0%	11%
Omeprazole	1%	8%	19%	0%	0%	18%
Pantoprazole	0%	11%	0%	0%	0%	25%
Citalopram	1%	6%	7%	6.6%	0%	12%
Fluoxetine	39%	21%	18%	14%	9%	11%
Paroxetine	1%	15%	8%	26%	34%	18%
Sertraline	0%	5%	10%	19%	0%	10%

Source: The authors, based on IMS data.

Figure 7.1

Denmark: Price movements of locally sourced versus parallel imported medicines for the most highly traded products, 1997-2002. 1,2

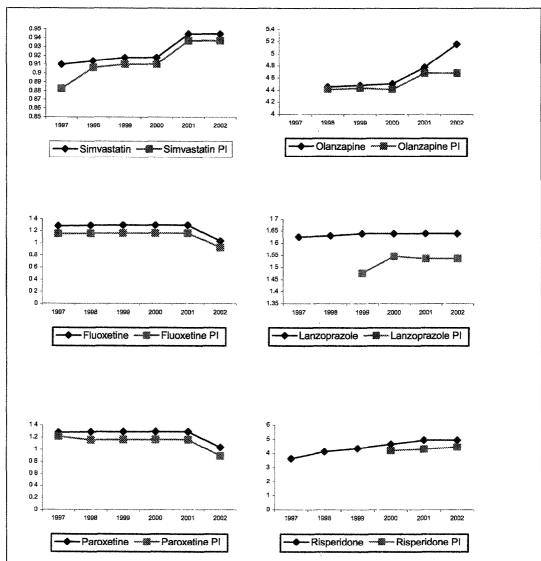


¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices.

² The hypothesis of no co-movement in prices is rejected for all four products, suggesting that price differences persist over time. The values of the t-statistics (all of them not statistically significant) and correlation coefficients (r) for each of the above products were as follows:

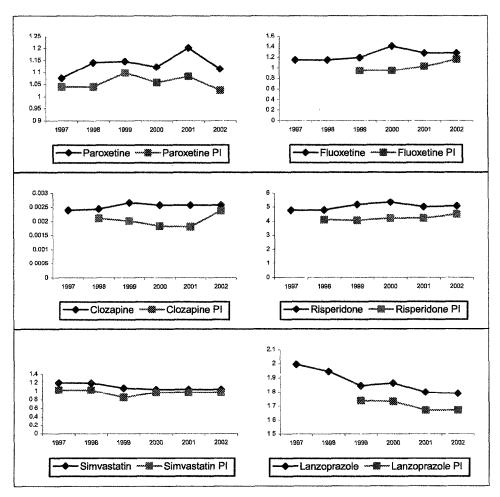
- 1. Clozapine t = 0.07, r = 0.99;
- 2. Risperidone t = 0.59, r = 1;
- 3. Simvastatin t = 0.13, r = 1;
- 4. Ramipril t = 0.54, r = 0.82.

Figure 7.2
Germany: Price movements of locally sourced versus parallel imported medicines for the most highly traded products, 1997-2002. 1,2



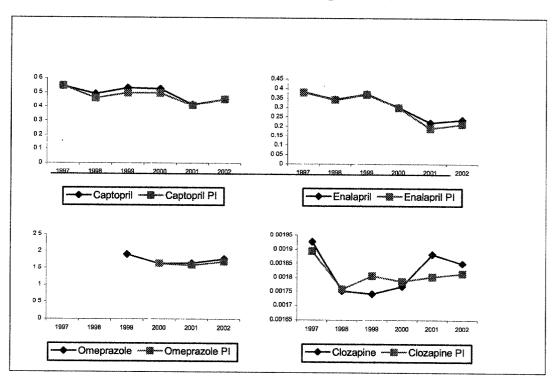
Notes: ¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices. ² The hypothesis of no co-movement in prices is rejected for all six products, suggesting that price differences persist over time; the results of the t-ratios are: Simvastatin: t=1.02; Olanzapine: t=1.41; Fluoxetine: t=0.96; Lansoprazole: t=0.47; Paroxetine: t=1.6; and Risperidone: t=1.0, all of which are not statistically significant.

Figure 7.3
The Netherlands: Price movements of locally sourced versus parallel imported medicines for the most highly traded products, 1997-2002.^{1,2}



- ¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices.
- ² The hypothesis of no co-movement in prices is rejected for all six products, suggesting that price differences persist over time. The values of the t-statistics (all of them not statistically significant) and correlation coefficients (r) for each of the above products were as follows:
- 1. Paroxetine t = 0.02, r = 0.99;
- 2. Fluoxetine t = 0.38, r = 0.99;
- 3. Clozapine t = 0.07 r = 0.96;
- 4. Risperidone t = 0.1 r = 0.99;
- 5. Simvastatin t = 0.05 r = 0.99;
- 6. Lansoprazole t = 0.27, r = 0.99.

Figure 7.4 Norway: Price movements of locally sourced versus parallel imported medicines for the most highly traded products, 1997-2002. 1,2



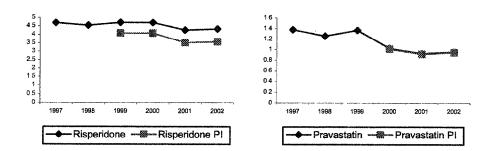
¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices.

² The hypothesis of no so movement in prices is rejected for the contract of the prices in the prices is rejected for the contract of the prices is rejected for the contract of the prices is rejected for the prices is rejected for the prices in the prices is rejected for the prices in the prices in the prices is rejected for the prices in the prices in the prices in the prices is rejected for the prices in the prices in the prices is rejected for the prices in the prices i

² The hypothesis of no co-movement in prices is rejected for all four products, suggesting that price differences persist over time. The values of the t-statistics (all of them not statistically significant) and correlation coefficients (r) for each of the above products were as follows:

- 1. Captopril t = 0.01, r = 0.96;
- 2. Enalapril t = 0.08, r = 0.98;
- 3. Omeprazole t = 0.40, r=1;
- 4. Clozapine t = 0.04, r = 0.76.

Figure 7.5
Sweden: Price movements of locally sourced versus parallel imported medicines in the most highly traded products, 1997-2002. 1,2

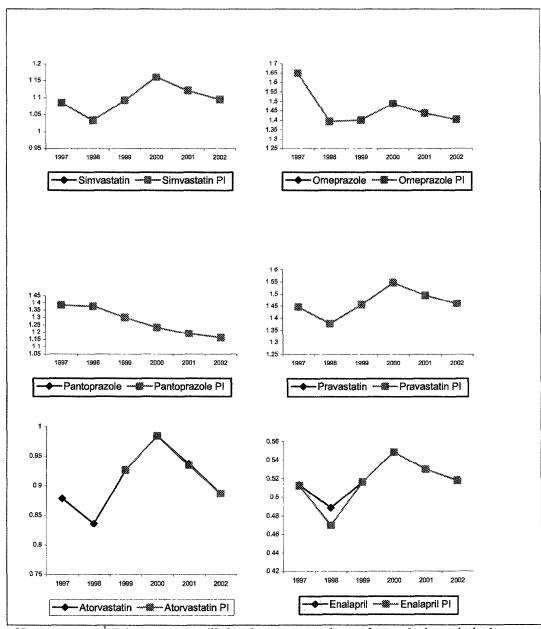


¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices.

² The hypothesis of no co-movement in prices is rejected for both products, suggesting that price differences persist over time. The values of the t-statistics (all of them not statistically significant) and correlation coefficients (r) for each of the above products were as follows:

- 1. Risperidone t = 0.33, r = 0.99;
- 2. Pravastatin t = 0.45, r = 1.

Figure 7.6
United Kingdom: Price movements of locally sourced versus parallel imported medicines for the most highly traded products, 1997-2002.^{1,2}



¹ Prices are per pill for the most popular pack matched precisely between locally sourced and PI drug DDD adjusted if necessary. Prices are public (retail) prices.

² The values of t-statistics and correlation coefficients (*r*) were for all products r=1 & t=0 except for Atorvastatin t=0.32, r=0.92; and Pravastatin t=0.24, r=0.98).

Table 8.1
Relative Price Ratios (RPR) for each importing country in relation to the lowest exporting country (prices are adjusted by DDD and pack size); 1997-2002

>00000000000000000000000000000000000000	1998	1999	2000	2001	2002
	HMG C	A Reductas	e inhibitors	(statins)	
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Atory	estatin		
Denmark	1.23	1.23	1.25	1.32	1.33
Germany	2.13	2.12	2.18	2.43	2.43
Netherlands	1.39	1.45	1.54	1.75	1.74
Norway	1.18	1.26	1.19	1.34	1.45
Sweden	1.80	1.88	1.81	1.97	1.99
UK	1.46	1.61	1.75	1.86	1.76
		Praya	statin		
Denmark	2.34	2.39	2.34	2.26	2.37
Germany		3.89	3.82	3.82	3.82
Netherlands	3.34	2.84	2.66	2.54	2.54
Norway	2.39	2.69	2.81	2.84	3.09
Sweden	3.18	3.60	2.70	2.44	2.52
UK	1.46	1.61	1.75	1.86	1.76
		Simva	statin	4 3 7	
Denmark	1.33	1.33	1.38	1.38	1.31
Germany	1.53	1.54	1.61	1.61	1.65
Netherlands	2.01	2.01	1.88	1.82	1.82
Norway	2.37	2.13	2.40	2.15	2.17
Sweden			1.81	1.79	1.81
UK	1.82	1.74	1.91	2.03	1.96

Table 8.1 (continued)

ACCORDED SELECTION OF THE SELECTION OF T	1997	1998	1999	2000	2001	2002
		AC	E I Inhibit	ors		
			Captopril		4 8 5	
Denmark	0.92	0.98	1.02	1.11	1.63	1.78
Germany	1.87	1.68	1.65	1.80	2.17	1.06
Netherlands	1.64	1.64	1.53	1.71	1.92	2.06
Norway	1.49	1.34	1.51	1.63	1.56	1.89
Sweden	N/a	N/a	N/a	N/a	N/a	N/a
UK	1.32	1.28	1.40	1.53	1.48	1.45
			Enalapril		Hill Bre	
Denmark	1.33	1.33	1.38	1.38	1.31	1.31
Germany	1.53	1.54	1.61	1.61	1.65	1.65
Netherlands	2.01	2.01	1.88	1.82	1.82	1.82
Norway	2.37	2.13	2.40	2.15	2.17	2.36
Sweden	N/a	N/a	1.81	1.79	1.81	N/a
UK	1.82	1.74	1.91	2.03	1.96	1.92
)uinalapril			
Denmark	N/a	1.64	1.77	1.76	1.97	1.98
Germany	N/a	1.91	2.30	2.30	2.30	2.30
Netherlands	N/a	4.64	4.73	4.50	4.67	4.69
Norway	N/a	N/a	N/a	N/a	N/a	N/a
Sweden	N/a	2.47	2.90	2.89	2.62	2.71
UK	N/a	1.74	1.90	2.02	1.95	1.91
			Ramipril			
Denmark	N/a	1.23	1.23	1.25	1.32	1.33
Germany	N/a	2.13	2.12	2.18	2.43	2.43
Netherlands	N/a	1.39	1.45	1.54	1.75	1.74
Norway	N/a	1.18	1.26	1.19	1.34	1.45
Sweden	N/a	1.80	1.88	1.81	1.97	1.99
UK	N/a	1.46	1.61	1.75	1.86	1.76

Table 8.1 (continued)

>>************************************	1997	1998	1999	2000	2001	2002			
ACE II inhibitors									
		Losa	rtan		299 70	444 1			
Denmark	N/a	1.51	1.52	1.49	1.22	1.24			
Germany	N/a	1.13	1.06	1.09	1.09	0.48			
Netherlands	N/a	1.10	0.99	1.03	0.97	0.93			
Norway	N/a	1.11	1.03	1.02	1.27	1.17			
Sweden	N/a	1.36	1.48	1.45	1.96	2.69			
UK	N/a	1.20	1.09	1.00	1.03	1.05			

Table 8.1 (continued)

nandroog#9550/https://documents.com/security/com/security	1997	1998	1999	2000	2001	2002
	Pro	ton Pum	p Inhibit	ors	***** *********************************	
1 1 1 1 5 1 1 1		Lansor	razole		() () () ()	1 1 1 1 1 1 1 1
Denmark	1.14	1.12	1.08	1.07	1.06	1.06
Germany	1.67	1.64	1.63	1.68	1.69	1.69
Netherlands	2.05	1.96	1.84	1.91	1.85	1.84
Norway	1.82	1.65	1.72	1.28	1.23	1.33
Sweden	N/a	N/a	N/a	1.55	1.12	1.14
UK	1.42	1.38	1.38	1.27	1.23	1.20
		18 30 Sec.				
Denmark	2.36	N/a	N/a	N/a	N/a	N/a
Germany	3.10	3.12	3.36	3.36	3.96	N/a
Netherlands	3.86	3.86	4.11	N/a	N/a	N/a
Norway	N/a	N/a	4.07	3.49	4.15	4.46
Sweden	12.12	11.42	12.33	12.29	13.10	13.32
UK	3.25	2.75	2.98	3.17	3.60	3.52
				4,40,00		
Denmark	1.11	0.99	0.93	0.83	0.72	0.66
Germany	N/a	N/a	N/a	N/a	1.70	1.79
Netherlands	1.71	1.65	1.54	1.55	1.42	1.50
Norway	1.67	1.43	1.44	1.42	1.37	1.08
Sweden	4.37	4.05	4.01	4.00	3.49	3.73
UK	1.29	1.22	1.11	1.05	0.97	1.00

Table 8.1 (continued)

	1997	1998	1999	2000	2001	2002
	Aty	pical ant	ipsycho	tics	***************************************	***************************************
		and the second s	apine			,
Denmark	N/a	N/a	N/a	1.13	1.12	1.16
Germany	1.34	1.44	1.43	1.56	1.70	1.70
Netherlands	1.60	1.72	1.90	1.84	1.88	1.58
Norway	1.67	1.66	1.68	1.36	1.38	1.48
Sweden	1.84	1.86	1.84	1.89	1.72	1.75
UK	1.47	1.57	1.52	1.66	1.61	1.58
		Risper	idone		1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	7.37
Denmark	1.019	1.294	1.285	1.428	1.192	1.194
Germany	1.660	2.109	2.099	2.283	2.482	2.482
Netherlands	1.773	2.257	2.409	2.552	2.414	2.438
Norway	1.565	1.844	1.914	1.630	1.657	1.800
Sweden	1.749	2.141	2.195	2.249	2.051	2.085
UK	1.607	2.019	2.121	2.312	2.247	2.196
		Cloza	pine		9 9 9	
Denmark	1.33	1.39	1.38	1.41	1.76	1.80
Germany	N/a	2.81	2.24	2.29	2.31	2.31
Netherlands	2.28	2.42	2.61	2.60	2.62	2.62
Norway	1.84	1.74	1.72	1.79	1.92	1.88
Sweden	N/a	N/a	2.25	2.27	2.02	2.06
UK	6.66	6.90	7.25	7.91	8.41	8.21

Product	Norway	Germany	Sweden	Denmark	UK	Netherlands
Atorvastatin	×	×	×	×	X	×
Pravastatin	×	0	\checkmark	0	X	✓
Simvastatin	×	×	0	0	X	✓
Captopril	×	✓	✓	×	✓	×
Enalapril	0	×	0	0	×	✓
Quinalapril	N/A	×	0	×	X	×
Ramipril	×	×	×	×	×	×
Losartan	0	✓	X	✓	√	✓
Valsartan	✓	✓	0	✓	0	✓
Clozapine	0	√	✓.	×	X	×
Olanzapine	✓	×	0	0	0	0
Risperidone	×	×	×	0	×	×
Citalopram	0	0	0.	√	0	0
Fluoxetine	0	0	✓	N/A	N/A	N/A
Paroxetine	0	✓	✓	0	0	✓
Sertraline	✓ ′	0	N/A	0	N/A	N/A
Lansoprazole	✓	0	N/A	0	0	√
Omeprazole	×	×	✓	N/A	×	×
Pantoprazole	✓	×	0	✓	✓	✓

¹ Adjusted by DDD and pack size.

✓= Tendency towards price convergence.

 \mathbf{X} = Tendency towards price divergence.

0 = Neither tendency towards price convergence nor tendency towards price divergence.

Source:

The authors, based on IMS data.